Agency 68

Kansas State Board of Pharmacy

Articles

Article 1.—REGISTRATION AND EXAMINATION OF PHARMACISTS

68-1-1. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-1-1a. Application for registrations or permits; withdrawal of application. After an application for a registration or permit has been accepted, the failure of the applicant or authorized representative to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application. (Authorized by and implementing K.S.A. 65-1630 and K.S.A. 2000 Supp. 65-1631; effective, E-76-31, Aug. 11, 1975; effective May 1, 1976; amended May 1, 1978; amended May 1, 1983; amended June 6, 1994; amended March 20, 1995; amended May 31, 2002.)

68-1-1b. Continuing educational unit. (a) Ten clock-hours of continuing education approved by the board shall constitute one continuing educational unit (C.E.U.). "Continuing education" shall mean an organized and systematic education experience beyond basic preparation that is designed to achieve the following:

(1)(A) Increase knowledge, improve skills, or enhance the practice of pharmacy; or

(B) improve protection of the public health and welfare; and

(2) ensure continued competence.

(b) Three C.E.U.s shall be required for renewal during each licensure period. Continuing education hours may be prorated for licensure periods that are less than biennial at a rate of .125 C.E.U.s per month.

(c)(1) Each continuing education program recognized by the accreditation council for pharmacy education (ACPE) shall be approved by the board.

(2) Each continuing education program shall be a program of continuing education that has been approved by the board. Each continuing education program shall be submitted to the board at least 120 days in advance for consideration for

approval. Except for continuing education programs recognized by the ACPE and approved by the board, continuing education programs shall not include in-service programs, on-the-job training, orientation for a job, an education program open to the general public, a cardiopulmonary resuscitation (CPR) course, a basic cardiac life support (BCLS) course, emergency or disaster training or direct experience at a healthcare facility under a code blue, testing out of a course, medical school courses, and continuing medical education (CME) category 1 programs.

(3) Continuing education credit received from any provider not recognized by the ACPE may be approved by the board after review and consideration of the following documentation submitted to the board by each licensee:

(A) A copy of the certification of attendance of completion for the program, which shall include the program title, type of course or program, name of provider, and the number of continuing education units completed; and

(B) a brief summary of the program stating the program's objectives and describing the relevance of the program to the practice of pharmacy.

(d) Attendance at a scheduled board meeting shall be accepted by the board for C.E.U. credit according to this schedule:

(1) 0.1 C.E.U. for each two hours of attendance at a scheduled board meeting; and

(2) a maximum of 0.8 C.E.U. for a biennial licensing period.

(e) A licensee shall not be allowed to carry forward excess hours earned in one licensure period into the next licensure period. (Authorized by and implementing K.S.A. 65-1632; effective, E-76-31, Aug. 11, 1975; effective May 1, 1976; amended May 1, 1978; amended May 1, 1983; amended May 1, 1986; amended May 1, 1987; amended July 1, 1990; amended July 31, 1998; amended Oct. 20, 2006.)

68-1-1c. (Authorized by and implementing K.S.A. 1982 Supp. 65-1631; effective May 1, 1983; revoked May 1, 1987.)

68-1-1d. Approved schools. The following may be recognized and approved by the board: (a) Any school or college of pharmacy or department of a university accredited by the accreditation council for pharmacy education; and

(b) any other school or college of pharmacy or department of a university that, as determined by the board, has a standard of education not below that of the university of Kansas school of pharmacy. (Authorized by and implementing K.S.A. 65-1631; effective May 1, 1983; amended May 1, 1987; amended Oct. 20, 2006.)

68-1-1e. (Authorized by and implementing K.S.A. 65-1631; effective May 1, 1983; amended May 1, 1987; revoked March 22, 2002.)

68-1-1f. Foreign graduates. (a) Each applicant who has graduated from a school or college of pharmacy or a pharmacy department of a university located outside of the United States or who is not a citizen of the United States shall provide proof that the applicant has reasonable ability to communicate verbally and in writing with the general public in English as specified in this regulation.

(b) Each foreign applicant shall be required to meet one of the following English language requirements for licensure under the pharmacy act of the state of Kansas:

(1) Pass the test of English as a foreign language (TOEFL) with a score of at least 570 and the test of spoken English (TSE) with a score of at least 50; or

(2) pass the internet-based TOEFL (iBT) as specified in K.A.R. 68-1-1g. (Authorized by and implementing K.S.A. 65-1631; effective May 1, 1983; amended June 6, 1994; amended March 20, 1995; amended Aug. 1, 1997; amended Oct. 20, 2006.)

68-1-1g. Internet-based TOEFL Except as specified in K.A.R. 68-1-1f, each foreign applicant shall be required to meet the English language requirement for licensure under the pharmacy act of the state of Kansas by passing the internet-based TOEFL (iBT) with at least the following minimum scores:

(a) 24 in writing;

(b) 26 in speaking;

(c) 18 in listening; and

(d) 21 in reading. (Authorized by and implementing K.S.A. 65-1631; effective Oct. 20, 2006.)

68-1-2. Grades required. (a) Each successful applicant for licensure by examination under the pharmacy act of the state of Kansas shall:

(1) pass an examination approved by the board; and

(2) obtain a grade of not less than 75% on the law examination administered by the board.

(b) Each successful applicant for licensure by reciprocity from another state shall score not less

than 75% on the law examination administered by the board.

(c) This regulation shall be effective on May 1, 1989. (Authorized by and implementing K.S.A. 1987 Supp. 65-1631(c), as amended by L. 1988, Ch. 243, Sec. 7; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended May 1, 1978; amended May 1, 1980; amended May 1, 1985; amended May 1, 1986; amended May 1, 1989.)

68-1-2a. Pharmacist-in-charge examination; acknowledgment. (a) Each prospective pharmacist-in-charge shall take a pharmacy law examination administered by the board, with a passing score of at least 85%. The examination shall include the statutes and rules and regulations, both state and federal, governing the practice of pharmacy.

(b) Each pharmacy or registrant required to have a pharmacist-in-charge that operates for more than 30 days without a designated pharmacist-in-charge who meets the requirements of this regulation shall be deemed to be in violation of K.S.A. 65-1627(e) and amendments thereto.

(c) A pharmacist who has already passed the pharmacist-in-charge examination required by the board shall not be required to retake the examination upon assuming the duties of a pharmacist-in-charge but shall, at the time of assuming these duties, sign an acknowledgment that states both of the following:

(1) The pharmacist is not currently prevented from performing the duties of a pharmacist-in-charge by an order of the board.

(2) The pharmacist has reviewed the pharmacy act and the board's regulations and is aware of the responsibilities of a pharmacist-in-charge.

The pharmacist-in-charge shall immediately provide this acknowledgment to the board. A copy of the acknowledgment shall be maintained at the premises where the pharmacist is functioning as a pharmacist-in-charge. (Authorized by K.S.A. 2000 Supp. 65-1643 and K.S.A. 2000 Supp. 65-1627; implementing K.S.A. 2000 Supp. 65-1643, K.S.A. 2000 Supp. 65-1627 and K.S.A. 2000 Supp. 65-1626, as amended by L. 2001, ch. 31, sec. 1; effective Aug. 1, 1997; amended May 31, 2002.)

68-1-3. (Authorized by and implementing K.S.A. 65-1630; effective Jan. 1, 1966; amended Jan. 1, 1967; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended May 1, 1978; amended May 1, 1983; revoked March 22, 2002.)

68-1-3a. Qualifying pharmaceutical experience. (a) Pharmaceutical experience that qualifies as one year of experience shall consist of 1,500 clock-hours as a pharmacy student or registered intern while being supervised by a preceptor. A preceptor may supervise no more than two individuals who are pharmacy students or interns at any time. All hours worked when the pharmacy student or intern is in regular attendance at an approved school of pharmacy and during vacation times and other times when the pharmacy student or intern is enrolled but not in regular attendance at an approved school of pharmacy may be counted as qualified hours. However, not more than 60 hours shall be acquired in any one week.

(b) No time may accrue to a pharmacy student before acceptance in an approved school of pharmacy or before being registered as an intern with the board. However, any foreign pharmacy graduate who has successfully passed an equivalent examination as specified in K.A.R. 68-1-1f (b) may apply for registration as an intern.

(c) Once registered as an intern, the intern shall complete all required hours within six years.

(d) Reciprocity shall not be denied to any applicant who is otherwise qualified and who meets either of the following conditions:

(1) Has met the internship requirements of the state from which the applicant is reciprocating; or

(2) has at least one year of experience as a registered pharmacist. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2003 Supp. 65-1626(g) and K.S.A. 65-1631; effective, E-76-31, Aug. 11, 1975; effective May 1, 1976; amended May 1, 1983; amended May 1, 1985; amended May 31, 2002; amended Jan. 14, 2005.)

68-1-4. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-1-5. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; revoked May 1, 1987.)

68-1-6. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-1-7. Reinstatement after lapse. Upon failure of a pharmacist to renew a registration under the provisions of K.S.A. 65-1632 for three consecutive years or more, the board shall require the applicant to take a written or oral examination

prior to reinstatement. Upon satisfactory completion of that examination and compliance with the provisions of K.S.A. 65-1632, the applicant shall be entitled to a renewal of registration if no grounds exist for denying the renewal. (Authorized by and implementing K.S.A. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended May 1, 1983.)

68-1-8. Registered pharmacist to be on duty. It shall be the duty of the pharmacist in charge of every premise having a pharmacy registration, to ensure that a registered pharmacist is on duty at all times during which the pharmacy is open. (Authorized by and implementing K.S.A. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended May 1, 1978; amended May 1, 1983.)

Article 2.—DRUGSTORES

68-2-1 to 68-2-4. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-2-5. Pharmacist-in-charge; notice to board. Each pharmacist shall notify the board in writing within five days of ceasing to serve as the pharmacist-in-charge at a pharmacy or registrant required to have a pharmacist-in-charge. The notice shall include the pharmacist's name, the name and address of the pharmacy or registrant, and the date the pharmacist ceased to serve as the pharmacist-in-charge. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2000 Supp. 65-1626(t) and K.S.A. 2000 Supp. 65-1643(a); effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended May 1, 1978; amended May 1, 1988; amended Aug. 1, 1997; amended March 22, 2002.)

68-2-6 to 68-2-8. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-2-9. Change of ownership; duty of registrant to notify board. Each registrant shall notify the executive secretary of the board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 Supp. 65-1643; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended May 1, 1978; amended Aug. 1, 1997; amended Feb. 7, 2003.)

68-2-10. Cessation of operations. Each registrant that ceases operations at the particular location for which the registration was received shall, within five days after termination of operations at that location, deliver to the executive secretary of the board the registration and a written explanation of the disposition of the remaining stocks of drugs. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 Supp. 65-1643; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended Feb. 7, 2003.)

68-2-11. Security. Each premises for which a pharmacy registration is issued, except medical care facilities, shall be constructed so that the pharmacy can be secured to prevent access to prescription-only drugs when a pharmacist is not on duty. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 Supp. 65-1637 and K.S.A. 2001 Supp. 65-1643; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended Feb. 7, 2003.)

68-2-12. (Authorized by K.S.A. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended May 1, 1978; revoked May 1, 1983.)

68-2-12a. Minimum requirements for library, equipment, and supplies. (a) Each registered pharmacy, other than a medical care facility pharmacy, shall have a reference library, either immediately accessed by a computer or printed, that is updated at least annually and that includes the following:

(1) A current copy of the Kansas pharmacy practice act, the Kansas uniform controlled substances act, and the regulations under both acts;

(2) a drug information reference specifically drafted for patients, which may include the "professional's guide to patient drug facts," published by facts and comparisons, or "United States pharmacopeia dispensing information," volume II;

(3) one recognized reference in toxicology, pharmacology, and drug interactions;

(4) one recognized reference in drug equivalencies; and

(5) a medical dictionary.

(b) Each registered pharmacy shall also have on the premises the equipment and supplies necessary to compound, dispense, label, administer, and distribute drugs. The equipment shall be in good repair and shall be available in sufficient quantities to meet the needs of the practice of pharmacy conducted there. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 Supp. 65-1642; effective May 1, 1983; amended May 1, 1986; amended May 1, 1987; amended April 30, 1990; amended March 20, 1995; amended Dec. 27, 1999; amended Feb. 7, 2003.)

68-2-13. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-2-14. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; revoked May 1, 1987.)

68-2-15. Nametags. (a) The following individuals shall wear a visible nametag under the following conditions:

(1) Each pharmacist, pharmacy student, and intern, while performing pharmacist functions in a pharmacy; and

(2) each pharmacy technician, while performing pharmacy technician functions in a pharmacy.

(b) Each nametag shall include the person's name and the designation of whether the person is a pharmacist, a pharmacy student, an intern, or a pharmacy technician. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 Supp. 65-1642; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended April 18, 2003.)

68-2-16. Branches, agents and pickup stations. No pharmacy nor pharmacist shall have, participate in, or permit an arrangement, branch, connection or affiliation whereby prescriptions are solicited, accepted, collected, or picked up, or advertised to be such, from or at any location other than a pharmacy for which a registration in good standing has been issued by the board. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976.)

68-2-17. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-2-18. (Authorized by K.S.A. 65-1630; effective Jan. 1, 1966; revoked May 1, 1987.)

68-2-19. Prescription copies. (A) No registered pharmacist shall fill, and no pharmacy shall permit the filling of, a copy of a prescription. (B) Every reference copy of a prescription shall bear the following legend—"This prescription copy is issued for reference only." (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976.)

68-2-20. Pharmacist's function in filling a prescription. (a) Those judgmental functions that constitute the filling or refilling of a prescription shall be performed only by a licensed pharmacist or by a pharmacy student or intern under the direct supervision of a licensed pharmacist and shall consist of the following steps:

(1) Read and interpret the prescription of the prescriber;

(2) limit any filling or refilling of a prescription to one year from the date of origin, except as provided by K.S.A. 65-1637, and amendments thereto;

(3) verify the compounding, counting, and measuring of ingredients and document the accuracy of the prescription;

(4) identify, in the pharmacy record, the pharmacist who verifies the accuracy of the completed prescription;

(5) personally offer to counsel each patient or the patient's agent with each new prescription dispensed, once yearly on maintenance medications and, if the pharmacist deems appropriate, with prescription refills in accordance with subsection (b);

(6) ensure the proper selection of the prescription medications, devices, or suppliers as authorized by law;

(7) when supervising a pharmacy technician, delegate only nonjudgmental duties associated with the preparation of medications and conduct in-process and final checks;

(8) prohibit all other pharmacy personnel from performing those judgmental functions restricted to the pharmacist; and

(9) interpret and verify patient medication records and perform drug regimen reviews.

(b) In order to comply with paragraph (a)(5), the pharmacist or the pharmacy student or intern under the pharmacist's supervision shall perform the following:

(1) Personally offer to counsel each patient or the patient's agent with each new prescription dispensed, once yearly on maintenance medications and, if the pharmacist deems appropriate, with prescription refills;

(2) provide the verbal counseling required by this regulation in person, whenever practical, or by the utilization of a telephone service available to the patient or patient's agent. Any pharmacist may authorize an exception to the verbal counseling requirement on a case-by-case basis for refills, maintenance medications, or continuous medications for the same patient;

(3) when appropriate, provide alternative forms of patient information to supplement verbal patient counseling. These supplemental forms of patient information may include written information, leaflets, pictogram labels, video programs, and auxiliary labels on the prescription vials. However, the supplemental forms of patient information shall not be used as a substitute for the verbal counseling required by this regulation;

(4) encourage proper patient drug utilization and medication administration. The pharmacist shall counsel the patient or patient's agent on those elements that, in the pharmacist's professional judgment, are significant for the patient. These elements may include the following:

(A) The name and a description of the prescribed medication or device;

(B) the dosage form, dosage, route of administration, and duration of therapy;

(C) special directions and precautions for preparation, administration, and use by the patient;

(D) common side effects, adverse effects or interactions, or therapeutic contraindications that may be encountered; the action required if these effects, interactions, or contraindications occur; and any activities or substances to be avoided while using the medication;

(E) techniques for self-monitoring drug therapy;

(F) proper storage requirements; and

(G) action to be taken in the event of a missed dose; and

(5) expressly notify the patient or the patient's agent if a brand exchange has been exercised.

(c) Nothing in this regulation shall be construed to require a pharmacist to provide the required patient counseling if either of the following occurs:

(1) The patient or the patient's agent refuses counseling.

(2) The pharmacist, based upon professional judgment, determines that the counseling may be detrimental to the patient's care or to the relationship between the patient and the patient's prescriber. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 Supp. 65-1637 and K.S.A. 2001 Supp. 65-1642; effective, E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1978; amended May 1, 1988; amended Nov. 30, 1992; amended March 20, 1995; amended Aug. 14, 1998; amended Dec. 27, 1999; amended Feb. 7, 2003.)

68-2-21. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1984 Supp. 65-1642; effective May 1, 1986; revoked May 1, 1987.)

68-2-22. Electronic prescription transmission. (a) Each prescription drug order transmitted electronically shall be issued for a legitimate medical purpose by a prescriber acting within the course of legitimate professional practice.

(b) Each prescription drug order communicated by way of electronic transmission shall meet these requirements:

(1) Be transmitted to a pharmacist in a licensed pharmacy of the patient's choice, exactly as transmitted by the prescriber;

(2) identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission, as well as any other information required by federal and state laws and regulations;

(3) be transmitted by an authorized prescriber or the prescriber's designated agent; and

(4) be deemed the original prescription drug order, if the order meets the requirements of this regulation.

(c) Any prescriber may authorize an agent to communicate a prescription drug order orally or electronically to a pharmacist in a licensed pharmacy, if the identity of the transmitting agent is included in the order.

(d) Each pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order communicated by way of electronic transmission, consistent with existing federal and state laws and regulations.

(e) All electronic equipment for receipt of prescription drug orders communicated by way of

electronic transmission shall be maintained so as to ensure against unauthorized access.

(f) Persons other than those bound by a confidentiality agreement shall not have access to pharmacy records containing confidential information or personally identifiable information concerning the pharmacy's patients.

(g) If communicated by electronic transmission, the prescription drug order shall be maintained in hard copy for the time required by existing federal or state laws and regulations, whichever is longer.

(h) Any prescription drug order, including that for any controlled substance listed in Schedules III, IV, and V and, in certain situations, that for any controlled substance listed in Schedule II, may be communicated by way of electronic transmission, if all requirements of K.A.R. 68-20-10a are met.

(i) After the pharmacist views the prescription drug order, this order shall be immediately reduced to a hard copy and shall contain all information required by federal and state laws and regulations. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2004 Supp. 65-1642; effective Feb. 5, 1999; amended Dec. 27, 1999; amended June 2, 2006.)

Article 3.—RETAIL DEALER'S PERMIT

68-3-1. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-3-2. (Authorized by K.S.A. 1977 Supp. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; revoked May 1, 1978.)

68-3-3 and 68-3-4. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-3-5. Retail dealer permit required. A retail dealer may engage in the selling in Kansas of nonprescription drugs that are prepackaged, fully prepared by the manufacturer or distributor for use by the consumer, and labeled in accordance with the requirements of the state and federal food, drug, and cosmetic acts only if the retail dealer has obtained a permit to do so from the board. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1998 Supp. 65-1643; effective Sept. 24, 1999.)

68-3-6. Minimum required information for permit. (a) Each retail dealer shall provide the board with the following minimum information as part of the application for the permit required by K.S.A. 65-1643(f), and amendments thereto, and as part of any renewal of this permit:

(1) The name, full business address, and telephone number of the permit holder;

(2) each trade or business name used by the permit holder; and

(3) the address, telephone number, and name of the contact person for each facility used by the permit holder for the storage, handling, and distribution of drugs.

(b) Each permit holder shall submit all revised information required by subsection (a) within 30 days after any change in that information. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1998 Supp. 65-1643; effective Sept. 24, 1999.)

Article 4.—MANUFACTURERS

68-4-1 to 68-4-4. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-4-5. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; revoked May 1, 1986.)

Article 5.—GENERAL RULES

68-5-1. Definitions. The following words and phrases as used throughout these rules and regulations shall have the meanings specified below, unless otherwise indicated by the context of the specific regulation.

(a) Beyond-use date. The term "beyond-use date" means a date placed on a prescription label at the time of dispensing, repackaging, or prepackaging that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(b) Intern. The word "intern" means an individual who is a prospective candidate for examination as a licensed pharmacist and who is qualified to receive and is obtaining pharmaceutical experience as set forth in the pharmacy act of the state of Kansas and its rules and regulations.

(c) Medication order. The term "medication order" means an order by a prescriber for a reg-

istered patient of a Kansas licensed medical care facility.

(d) Prescriber. The word "prescriber" means a person who is authorized to issue a prescription order. (Authorized by and implementing K.S.A. 65-1630; effective Jan. 1, 1966; amended Jan. 1, 1967; amended Jan. 1, 1968; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended May 1, 1988; amended April 28, 2000.)

68-5-2. (Authorized by K.S.A. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; revoked May 1, 1980.)

68-5-3 to 68-5-5. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-5-6. (Authorized by K.S.A. 1977 Supp. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended May 1, 1978; revoked May 1, 1987.)

68-5-7 and 68-5-8. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-5-9. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; revoked May 1, 1986.)

68-5-10. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; amended Jan. 1, 1968; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; revoked May 1, 1987.)

68-5-11. (Authorized by K.S.A. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; revoked April 10, 1989.)

68-5-12 and 68-5-13. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1966; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-5-14. (Authorized by K.S.A. 1977 Supp. 65-1630; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended May 1, 1978; revoked May 1, 1987.)

68-5-15. Training of pharmacy technicians. (a) The pharmacist-in-charge of any pharmacy in which one or more pharmacy technicians peform any tasks authorized by the pharmacy act shall insure that each pharmacy technician complies with the training requirements in this regulation.

(b) The pharmacist-in-charge of any pharmacy in which one or more pharmacy technicians perform any tasks authorized by the pharmacy act shall insure that there exists for the pharmacy a current pharmacy technician training course, designed for the functioning of that pharmacy and addressing at least the following:

(1) Knowledge and understanding of the different pharmacy practice settings;

(2) knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards, ethics, laws, and regulations governing the practice of pharmacy;

(3) knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations, and symbols commonly used in prescribing and dispensing drugs and in record keeping;

(4) knowledge of and the ability to carry out calculations required for common dosage determinations;

(5) knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms, storage requirements, and manufacturer recalls;

(6) knowledge of and the ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions or other drug distribution systems; and

(7) knowledge of and the ability to perform procedures and techniques, including aseptic techniques, relating to the compounding, packaging, and labeling of drugs.

(c) The pharmacist-in-charge of any pharmacy shall permit a pharmacy technician to perform tasks authorized by the pharmacy act only if the pharmacy technician has successfully completed, within 180 days of the effective date of this regulation or the effective date of the technician's employment in the pharmacy, whichever is later, a training course that meets the requirements of subsection (b) and was designed for the pharmacy in which the tasks are performed.

(d) The pharmacist-in-charge of any pharmacy in which one or more pharmacy technicians perform any tasks authorized by the pharmacy act shall also insure that the following requirements are met:

(1) There is an annual review of the pharmacy

technician training course developed for the pharmacy.

(2) Adequate records are maintained documenting the training of each pharmacy technician as required by this regulation. These records shall be maintained at the pharmacy in a manner available for inspection by a board representative.

(3) The board is notified, within 30 days of the effective date of this regulation or the effective date of the employment of a pharmacy technician, of the following:

(i) The full name and current residence address of pharmacy technicians working in a pharmacy for which the pharmacist-in-charge has responsibility;

(ii) the date on which the pharmacy technician began the pharmacy technician training course or courses designed for the pharmacy or pharmacies in which the pharmacy technician is working; and

(iii) the name and address of the pharmacy or pharmacies in which the pharmacy technician is working. (Authorized by K.S.A. 65-1630 and K.S.A. 1998 Supp. 65-1642; implementing K.S.A. 1998 Supp. 65-1642; effective July 23, 1999.)

68-5-16. Ratio of pharmacy technicians to pharmacists. (a) Except as otherwise provided in this regulation, the ratio of pharmacy technicians to pharmacists in the prescription area of any pharmacy shall not exceed two to one.

(b) The ratio of pharmacy technicians to pharmacists in the prescription area of any pharmacy may be three to one if at least two of the pharmacy technicians have a current certification issued by the pharmacy technician certification board or a current certification issued by any other pharmacy technician certification organization approved by the board. Any pharmacy technician certification organization may be approved by the board if the board determines that the organization has a standard for pharmacy technician certification and recertification not below that of the pharmacy technician certification board. (Authorized by and implementing K.S.A. 2005 Supp. 65-1663, as amended by L. 2006, ch. 40, sec. 1; effective, T-68-8-22-05, Aug. 22, 2005; effective May 26, 2006; amended April 27, 2007.)

Article 6.—POISONS; ADDITIONS AND DELETIONS TO STATUTORY LIST

68-6-1. (Authorized by K.S.A. 1977 Supp. 65-1638; effective Jan. 1, 1966; revoked May 1, 1978.)

68-6-2. (Authorized by K.S.A. 65-1638; effective Jan. 1, 1966; revoked May 1, 1980.)

Article 7.—MISCELLANEOUS PROVISIONS

68-7-1 to 68-7-6. (Authorized by K.S.A. 1975 Supp. 65-1630; effective Jan. 1, 1968; revoked, E-76-31, Aug. 11, 1975; revoked May 1, 1976.)

68-7-7. (Authorized by K.S.A. 1977 Supp. 65-1630; effective, E-76-31, Aug. 11, 1975; effective May 1, 1976; revoked May 1, 1978.)

68-7-8. Records. Original written prescriptions shall be deemed recordation in writing by the pharmacist under the provisions of K.S.A. 65-1637 (b) (1975 Supp.). (Authorized by K.S.A. 1975 Supp. 65-1630; effective, E-76-31, Aug. 11, 1975; effective May 1, 1976.)

68-7-9. (Authorized by K.S.A. 1977 Supp. 74-1606; effective, E-76-31, Aug. 11, 1975; effective May 1, 1976; amended May 1, 1978; revoked May 1, 1987.)

68-7-10. Pharmacy based drug distribution systems in adult care homes; definitions; emergency medication kits. (a) Definitions.

(1) "Adult care home" has the same meaning as set forth in K.S.A. 39-923.

(2) "Unit dose system" means a drug distribution system which is pharmacy-based and which uses unit dose containers that enable distribution of packaged doses in a manner that preserves the identity of the drug until the time of administration.

(3) "Traditional system" means a drug distribution system in which the pharmacist receives a prescription order for an individual patient and fills the prescription in any manner other than packaging individual doses in unit dose containers.

(4) "Unit dose container" means a single or multiple unit container for articles intended for administration in single doses, directly from the container, by other than parenteral route.

(A) "Multiple unit container" means a container that permits withdrawal of successive portions of the contents without changing the strength, quality, or purity of the remaining portion.

(B) "Single unit container" means a container that is designed to hold a quantity of a drug in-

tended for administration as a single dose promptly after the container is opened.

(b) All pharmacy-based drug distribution systems for adult care homes shall:

(1) Be consistent with the medication needs of the patient;

(2) conform to all federal and state laws and regulations pertaining to pharmacies; and

(3) conform to the following additional requirements:

(A) All prescriptions (unit dose or traditional) shall be dispensed from a pharmacy within a reasonable length of time after the medication is ordered.

(B) The supplying pharmacy shall be responsible for the safe delivery of drugs to a designated person or persons in the adult care home.

(C) The supplying pharmacy shall provide a method of identifying the date and quantity of medication dispensed.

(D) A patient medication profile record system shall be maintained for each adult care home patient serviced by the supplying pharmacy and shall contain the information necessary to allow the pharmacist to monitor each patient's drug therapy.

(E) All medication distribution system containers shall be labeled to permit the identification of the drug therapy.

(c) All unit dose drug distribution systems shall, in addition to the above requirements, conform to the following requirements:

(1) All medication shall be packaged in unit dose containers as far as practicable, and the packaging shall conform to the provisions of K.A.R. 68-7-15 and 68-7-16.

(2) The pharmacist shall be responsible for filling and refilling prescriptions or practitioner's orders or both according to the directions of the practitioner by relying on the original prescription or practitioner's order or a direct copy thereof.

(3) The pharmacist shall comply with all requirements for prescription orders, including inventory and record keeping requirements, under:

(A) The Kansas uniform controlled substances act, K.S.A. 65-4101 et seq.;

(B) the Kansas pharmacy act, K.S.A. 65-1601 et seq.;

(C) the applicable regulations in K.A.R. 68-20-1 et seq. and K.A.R. 68-1-1 et seq.; and

(D) all federal laws and regulations applicable to prescriptions or medication orders.

(4) Unit dose dispensing shall take place at the address of the pharmacy providing the unit dose system.

(5) Container requirements for unit-dose distribution systems may include trays, bins, carts and locked cabinets if the requirements of K.A.R. 68-7-14 are complied with. If these options are used, all patient medication trays or drawers shall be sufficiently labeled to identify the patient.

(6) Each unit dose distribution system shall provide a verification check at the point of patient administration in order to insure proper drug utilization.

(7) The delivery time-cycle or hours of exchange shall not be limited to a specific time, but shall depend upon the pharmacist's discretion, the needs of the adult care home, the stability of the drug, and the type of container used.

(8) The pharmacist or a pharmacy intern under the direct supervision of a pharmacist shall have sole responsibility for dispensing under the unit dose system.

(d) Emergency medication kits.

(1) Emergency medication kits shall contain only the drugs which are generally regarded by practitioners as essential to the prompt treatment of sudden and unforeseen changes in a patient's condition which present an imminent threat to the patient's life or well-being.

(2) Drugs to be contained within emergency medication kits shall be approved by the adult care home pharmaceutical services committee (or its equivalent) composed of at least a practitioner and a pharmacist.

(3) The emergency medication kit shall conform to the following requirements:

(A) The kit shall be supplied by a pharmacist who shall retain possession of the drug until it is administered to the patient upon the proper order of a practitioner.

(B) The kit shall be locked or sealed in a manner that obviously reveals when the kit has been opened or tampered with.

(C) The kit shall be securely locked in a sufficiently well-constructed cabinet or cart and access to the cabinet or cart shall be available only to the nurse or nurses as determined by the pharmaceutical services committee or its equivalent.

(D) The kit shall have an expiration date equivalent to the earliest expiration date of drugs within the kit, but in no event more than one year after all of the drugs were placed in the kit.

(E) All drugs contained within the emergency

medication kit shall be returned to the pharmacy as soon as the kit is opened, along with the practitioner's drug order for medications administered. (Authorized by and implementing K.S.A. 65-1648; effective May 1, 1978; amended May 1, 1983; amended Sept. 9, 1991.)

68-7-11. Medical care facility pharmacy. The scope of pharmaceutical services within a medical care facility pharmacy shall conform to the following requirements:

(a) The pharmacist-in-charge shall be responsible for developing programs and supervising all personnel in the distribution and control of drugs and all pharmaceutical services in the medical care facility.

(b) The pharmacist-in-charge shall develop a policy and procedure manual governing the storage, control, and distribution of drugs within the medical care facility. The pharmacist-in-charge shall submit the policy and procedure manual for approval to the pharmacy and therapeutics committee or an equivalent committee governing the security, control, and distribution of drugs within the facility.

(c) The pharmacist-in-charge shall be responsible for the maintenance of all emergency medication kits.

(d) The pharmacist-in-charge shall be responsible for developing procedures for the distribution and control of drugs within the medical care facility when a pharmacist is not on the premises. These procedures shall be consistent with the following requirements:

(1) Inpatient service. Drugs may be obtained upon a prescriber's medication order for administration to the inpatient by a designated registered professional nurse or nurses with approval and supervision of the pharmacist-in-charge. Adequate records of these withdrawals shall be maintained.

(2) Emergency outpatient service.

(A) An interim supply of prepackaged drugs shall be supplied to an outpatient only by a designated registered professional nurse or nurses pursuant to a prescriber's medication order when a pharmacist is not on the premises and a prescription cannot be filled. The interim supply shall be labeled with the following information:

(i) The name, address, and telephone number of the medical care facility;

(ii) the name of the prescriber. The label shall include the name of the practitioner and, if involved, the name of either the physician's assistant (PA) or the advanced registered nurse practitioner (ARNP);

(iii) the full name of the patient;

(iv) the identification number assigned to the interim supply of the drug or device by the medical care facility pharmacy;

(v) the date the interim supply was supplied;

(vi) adequate directions for use of the drug or device;

(vii) the beyond-use date of the drug or device issued;

(viii) the brand name or corresponding generic name of the drug or device;

(ix) the name of the manufacturer or distributor of the drug or device, or an easily identified abbreviation of the manufacturer's or distributor's name;

(x) the strength of the drug;

(xi) the contents in terms of weight, measure, or numerical count; and

(xii) necessary auxiliary labels and storage instruction, if needed.

(B) The interim supply shall be limited in quantity to an amount sufficient to supply the outpatient's needs until a prescription can be filled. Adequate records of the distribution of the interim supply shall be maintained and shall include the following information:

(i) The original or a copy of the prescriber's order, or if an oral order, a written record prepared by a designated registered professional nurse or nurses that reduces the oral order to writing. The written record shall be signed by the designated registered professional nurse or nurses and the prescriber; and

(ii) the name of the patient; the date supplied; the drug or device, strength, and quantity distributed; directions for use; the prescriber's name; and, if appropriate, the DEA number.

(3) The designated registered professional nurse or nurses may enter the medical care facility pharmacy and remove properly labeled pharmacy stock containers, commercially labeled packages, or properly labeled prepackaged units of drugs. The registered professional nurse shall not transfer a drug from one container to another for future use, but may transfer a single dose from a stock container for immediate administration to the ultimate user.

(e) The pharmacist-in-charge of the medical care facility pharmacy shall maintain documentation of at least quarterly checks of drug records

and conditions of drug storage, in all locations within the facility, including nursing stations, emergency rooms, outpatient departments, and operating suites.

(f) The pharmacist-in-charge shall participate with the pharmacy and therapeutics committee or an equivalent committee in formulating broad professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, and safety procedures for drugs within the medical care facility.

(g) The pharmacist-in-charge shall be responsible for establishing a drug recall procedure that can be effectively implemented.

(h)(1) The pharmacist-in-charge shall be responsible for developing written procedures for maintaining records of drug distribution, prepackaging, and bulk compounding. Prepackaged drugs shall include the following information:

(A) The brand name or corresponding generic name of the drug;

(B) the name of the manufacturer or distributor of the drug, or an easily identified abbreviation of the manufacturer's or distributor's name;

(C) the strength of the drug;

(D) the contents in terms of weight, measure, or numerical count;

(E) the lot number; and

(F) the beyond-use date.

(2) Prepackaged drugs shall be packaged in suitable containers and shall be subject to all other provisions of the Kansas state board of pharmacy regulations under the uniform controlled substances act of the state of Kansas and under the pharmacy act of the state of Kansas. Before releasing any drugs or devices from the pharmacy, the pharmacist shall verify the accuracy of all prepackaging and the compounding of topical and oral drugs.

(i) The pharmacist-in-charge shall ensure that the medical care facility maintains adequate drug information references commensurate with services offered and a current copy of the Kansas pharmacy act, the Kansas uniform controlled substances act, and current regulations under both acts.

(j) The pharmacist-in-charge shall be responsible for pharmacist supervision of all pharmacy technicians and for confining their activities to those functions permitted by the pharmacy practice act. Records shall be maintained describing the following:

(1) The training and related education for nondiscretionary tasks performed by pharmacy technicians; and

(2) written procedures designating the person or persons functioning as pharmacy technicians, describing the functions of the pharmacy technicians, and documenting the procedural steps taken by the pharmacist-in-charge to limit the functions of pharmacy technicians to nondiscretionary tasks.

(k) The pharmacist-in-charge shall be responsible for establishing policies and procedures for the mixing or preparation of parenteral admixtures. Whenever drugs are added to intravenous solutions, distinctive supplemental labels shall be affixed that indicate the name and amount of the drug added, the date and the time of addition, the beyond-use date, storage instructions, and the name or initials of the person who prepared the admixture. The pharmacist-in-charge shall comply with all requirements of K.A.R. 68-13-1. Before the parenteral admixture is released from the pharmacy, the pharmacist shall verify the accuracy of all parenteral admixtures prepared by pharmacy technicians.

(l) The pharmacist shall interpret the prescriber's original order, or a direct copy of it, before the drug is distributed and shall verify that the medication order is filled in strict conformity with the direction of the prescriber. This requirement shall not preclude orders transmitted by the prescriber through electronic transmission. Variations in this procedure with "after-the-fact" review of the prescriber's original order shall be consistent with medical care facility procedures established by the pharmacist-in-charge. Each medication order shall be reviewed by a pharmacist within seven days of the date it was written.

(m) Pharmacy services to outpatients during pharmacy hours shall be in accordance with the board's regulations, K.S.A. 65-1625 et seq., and K.S.A. 65-4101 et seq., and amendments thereto, governing community pharmacy practice.

(n) The pharmacist-in-charge shall be responsible for the security of the pharmacy, including the drug distribution systems and personnel.

(1) When a pharmacist is on the premises but not in the pharmacy, a pharmacy technician may be in the pharmacy. A pharmacy technician shall not distribute any drug or device out of the pharmacy when a pharmacist is not physically in the pharmacy unless authorized by the pharmacist.

(2) When a pharmacist is not on the premises, no one shall be permitted in the pharmacy except

the designated registered professional nurse or nurses.

(o) Each pharmacist-in-charge who will no longer be performing the functions of the pharmacist-in-charge position shall inventory all controlled substances in the pharmacy before leaving the pharmacist-in-charge position. A record of the inventory shall be maintained for at least five years.

(p) Within 72 hours after beginning to function as a pharmacist-in-charge, the pharmacist-in-charge shall inventory all controlled substances in the pharmacy. A record of the inventory shall be maintained for at least five years. (Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1648, K.S.A. 2006 Supp. 65-1642, and K.S.A. 2006 Supp. 65-1626; effective, E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1978; amended May 1, 1988; amended May 1, 1989; amended Dec. 27, 1999; amended April 28, 2000; amended July 20, 2007.)

68-7-12. Responsibility of pharmacist-in-charge in other than a medical care facility pharmacy. Each pharmacist-in-charge for premises having a pharmacy registration, other than a medical care facility pharmacy, shall be responsible for the following functions.

(a) Each pharmacist-in-charge shall develop, supervise, and coordinate all pharmaceutical services carried on within the pharmacy to ensure compliance with the Kansas pharmacy act, the Kansas uniform controlled substances act, federal drug laws, and all applicable regulations.

(b) Each pharmacist-in-charge shall be personally available to the extent required to ensure comprehensive pharmaceutical services within the pharmacy and to develop a staff of additional licensed pharmacists and supportive personnel as necessary to serve the needs of the pharmacy. Each pharmacist-in-charge shall maintain records in the pharmacy describing the training and education regarding work functions performed by all pharmacy personnel. Each pharmacist-in-charge shall maintain in the pharmacy written procedures that address the following areas:

(1) Designate the person or persons functioning as pharmacy technicians and supportive personnel;

(2) describe the functions of all personnel; and

(3) document the procedural steps taken by the pharmacist-in-charge to limit the functions of all personnel to their respective pharmacy work functions.

(c) Each pharmacist-in-charge shall develop or approve written policies and procedures for the pharmacy that meet all of the following conditions:

(1) Adequate accountability and control of drugs in compliance with the Kansas pharmacy act, the Kansas uniform controlled substances act, federal drug laws, and all applicable regulations are provided for.

(2) Any incident that occurs as a result of an alleged or real error in filling or dispensing a prescription or medication order is brought to the attention of the pharmacist-in-charge and completely documented in accordance with the requirements of K.A.R. 68-7-12b.

(3) Adequate records of the pharmacy's dispensing, prepackaging, and bulk compounding actions are maintained, and all prepackaging of drugs is done in suitable containers, properly labeled in accordance with K.A.R. 68-7-16.

(d) Each pharmacist-in-charge shall develop written procedures for maintaining records of the pharmacy's dispensing, prepackaging, and bulk compounding actions and shall ensure that prepackaged medication is packaged in suitable containers and properly labeled.

(e) A pharmacist-in-charge who will no longer be performing the functions of the pharmacist-in-charge position shall inventory all controlled substances in the pharmacy before leaving the pharmacist-in-charge position. A record of the inventory shall be maintained for at least five years.

(f) Within 72 hours after beginning to function as a pharmacist-in-charge, the pharmacist-in-charge shall inventory all controlled substances in the pharmacy. A record of the inventory shall be maintained for at least five years. (Authorized by K.S.A. 65-1630 and K.S.A. 2006 Supp. 65-1643; implementing K.S.A. 2006 Supp. 65-1626 and K.S.A. 2006 Supp. 65-1637; effective, E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1978; amended May 1, 1989; amended Nov. 30, 1992; amended Feb. 27, 1998; amended Dec. 27, 1999; amended Feb. 7, 2003; amended July 20, 2007.)

68-7-12a. Nonresident pharmacies. (a) Nonresident pharmacies shall meet the following requirements to be and remain registered in Kansas by the board.

(1) Each pharmacy shall be currently licensed or registered in good standing in the state in which it is located.

(2) Each pharmacist dispensing drugs into Kansas shall be licensed as a pharmacist in the state where the pharmacist practices.

(b) A pharmacist licensed in the state where the pharmacist practices shall be named in the application as the pharmacy's responsible pharmacist, who shall be responsible for receiving communications from the board.

(1) That pharmacist shall timely respond to any lawful request for information from the board or law enforcement authorities.

(2) That pharmacist shall be responsible for receiving and maintaining publications distributed by the board.

(3) If at any time the pharmacist so designated leaves the employment of the pharmacy, the owner or the owner's authorized representative of the pharmacy shall promptly notify the board and designate another pharmacist to perform this function.

(c) The owner or the owner's authorized representative of the nonresident pharmacy shall apply for registration and renewal on forms approved by the board. The information reasonably necessary to carry out the provisions of K.S.A. 65-1657 and amendments thereto, including the name, address, and position of each officer and director of a corporation or of the owners if the pharmacy is not a corporation, may be required by the board.

(d) An exemption for registration may be granted by the board under K.S.A. 65-1657 and amendments thereto, upon application by any nonresident pharmacy that confines its dispensing activity to isolated transactions. The following shall be considered to determine whether to grant an exemption:

(1) The number of prescriptions dispensed or reasonably expected to be dispensed into Kansas;

(2) the number of patients served or reasonably expected to be served in Kansas;

(3) any efforts to promote the pharmacy's services in Kansas;

(4) any contract between the pharmacy and either an employer or organization to provide pharmacy services to employees or other beneficiaries in Kansas;

(5) medical necessity;

(6) the effect on the health and welfare of persons in Kansas; and

(7) any other relevant matters.

(e) The pharmacy owner shall pay an annual registration fee as set forth in K.A.R. 68-11-2.

(f) The pharmacy records of drugs dispensed to Kansas addresses shall be maintained so that the records are readily retrievable upon request. These records shall be made available for inspection by the board or by Kansas law enforcement authorities upon request.

(g) The pharmacy shall maintain an incoming toll-free telephone number for use by Kansas customers to facilitate personal communication with a pharmacist with access to patient records.

(1) This service shall be available during normal business hours for a minimum of 40 hours and six days per week.

(2) This telephone number and any others available for use shall be printed on each container of drugs dispensed in Kansas.

(3) The toll-free number shall have a sufficient number of extensions to provide reasonable access to incoming callers.

(h) Generic drugs shall be dispensed into Kansas only pursuant to K.S.A. 65-1637(a), and amendments thereto.

(i) The facilities and records of the pharmacy shall be subject to inspection by the board. Satisfactory inspection reports by the licensing entity using similar standards of the state where the pharmacy is located may be accepted in lieu of inspection by the board.

(j) Each owner or owner's authorized representative of the nonresident pharmacy doing business in Kansas by dispensing and either delivering or causing to be delivered prescription drugs to Kansas consumers shall designate a resident agent in Kansas for service of process and file this information with the secretary of state. (Authorized by and implementing K.S.A. 2001 Supp. 65-1657; effective March 29, 1993; amended March 20, 1995; amended Feb. 7, 2003.)

68-7-12b. Incident reports. (a) For purposes of this regulation, "reportable incident" and "incident" shall mean a preventable medication error involving a prescription drug and resulting in any of the following:

(1) The patient receiving the wrong drug;

(2) the patient receiving an incorrect drug strength;

(3) the patient receiving an incorrect dosage form;

(4) the drug being received by the wrong patient;

(5) inadequate or incorrect packaging, labeling, or directions; or

(6) the dispensing of a drug to a patient in a situation that results in or has the potential to result in serious harm to the patient.

(b) For each pharmacy other than a medical care pharmacy, the pharmacist-in-charge shall ensure that procedures exist requiring each pharmacist who becomes aware of a reportable incident to report the incident to the pharmacist-in-charge as soon as practical.

(c) As soon as possible after discovery of the incident, the pharmacist shall prepare a report containing the following information:

(1) The name, address, age, and phone number of any complainant, if available;

(2) the name of each pharmacy employee and the license number of each licensee involved;

(3) the date of the incident and the date of the report;

(4) the pharmacist's description of the incident;

(5) the prescriber's name and whether or not the prescriber was contacted; and

(6) the signatures of all pharmacy employees involved in the incident.

For each pharmacy, the pharmacist-in-charge shall ensure that procedures exist requiring that the incident report be maintained in the pharmacy for at least five years in a manner so that the report can be provided to the board or its representative within three business days, upon request.

(d) The preparation of an incident report that meets the requirements of this regulation shall be the responsibility of each pharmacist involved in the incident and the pharmacist-in-charge. The maintenance of incident reports as required by this regulation shall be the responsibility of the pharmacist-in-charge. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2007 Supp. 65-1626 and K.S.A. 2007 Supp. 65-1626d; effective Feb. 7, 2003; amended Oct. 24, 2008.)

68-7-13. Pharmacist in charge of more than one location. No pharmacist shall be a pharmacist in charge of more than one full-time pharmacy operation, which is defined as being one where the on-premises pharmacist services total 30 hours or more weekly. (Authorized by and implementing K.S.A. 65-1630; effective, E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1988.)

68-7-14. Prescription labels. (a) The label of each drug or device shall be typed or machine-printed and shall include the following information:

(1) The name, address, and telephone number of the pharmacy dispensing the prescription;

(2) the name of the prescriber. The label shall include the name of the practitioner and, if involved, the name of either the physician's assistant (PA) or the advanced registered nurse practitioner (ARNP);

(3) the full name of the patient;

(4) the identification number assigned to the prescription by the dispensing pharmacy;

(5) the date the prescription was filled or refilled;

(6) adequate directions for use of the drug or device;

(7) the beyond-use date of the drug or device dispensed;

(8) the brand name or corresponding generic name of the drug or device;

(9) the name of the manufacturer or distributor of the drug or device, or an easily identified abbreviation of the manufacturer's or distributor's name;

(10) the strength of the drug;

(11) the contents in terms of weight, measure, or numerical count; and

(12) necessary auxiliary labels and storage instructions, if needed.

(b) A pharmacy shall be permitted to label or relabel only those drugs or devices originally dispensed from the providing pharmacy. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1999 Supp. 65-1626a; effective, E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1978; amended May 1, 1980; amended May 1, 1988; amended June 6, 1994; amended March 20, 1995; amended April 28, 2000.)

68-7-15. Prepackaging or repackaging of drugs. All prepackaging or repackaging of drugs, whether in a unit dose container or multiple dose container shall conform to the following:

(a) Packaging in advance of immediate need shall be done by a pharmacist or under his or her direct supervision.

(b) This packaging shall be limited to drugs to be dispensed from the premises.

(c) Proper storage conditions shall be main-

tained so as to preserve the stability of the drug as recommended by the manufacturer.

(d) A proper control system shall be established for lot numbers for recall purposes.

(e) If an area apart or separated from the prescription area is used for prepackaging or repackaging, such area must be enclosed and secured (locked) when a pharmacist is not in attendance in that area. (Authorized by K.S.A. 1977 Supp. 65-1630; effective May 1, 1978.)

68-7-16. Labels for prepackaged or repackaged drugs. Labels for prepackaged and repackaged drugs shall contain the following:

(a) The generic name with manufacturer and distributor's name or the brand name.

(b) Strength and quantity.

(c) Lot number and date repackaged and the person responsible for packaging.

(d) The expiration date, if applicable.

(e) Auxiliary labels necessary.

(f) Manufacturer, lot numbers, date repackaged, and the person responsible may be deleted from the label if a suitable record system is maintained to indicate them. (Authorized by K.S.A. 1977 Supp. 65-1630; effective May 1, 1978.)

68-7-17. (Authorized by K.S.A. 1977 Supp. 65-1630; effective Feb. 15, 1977; revoked May 1, 1978.)

68-7-18. Health departments and private not-for-profit family planning clinics. The distribution and control of drugs provided by health departments and private not-for-profit family planning clinics authorized under K.S.A. 65-1648(d)(1), and amendments thereto, shall conform to the following requirements:

(a) The approved drugs that may be stored and distributed by health departments and not-for-profit family planning clinics shall be only non-controlled drugs that are approved by the food and drug administration. In determining the formulary for each health department or not-for-profit family planning clinic, the pharmacist-in-charge shall consult with the medical supervisor and director of nursing for that facility. No state or federal controlled drugs shall be allowed.

(b)(1) The pharmacist-in-charge shall review the procedures outlined below for the distribution and control of all drugs within health department facilities and family planning clinics and shall be responsible for the following:

(A) Ensuring the development of programs for supervision of all personnel in the distribution and control of drugs;

(B) ensuring the development of a policy and procedure manual governing the storage, control, and distribution of drugs;

(C) maintaining documentation of at least quarterly checks of drug records, drug storage conditions, and drugs stored in all locations within the facility;

(D) establishing a drug recall procedure that can be effectively implemented; and

(E) ensuring the development of written procedures for maintaining records of distribution and prepackaging of drugs.

(2) Labels for prepackaged drugs shall contain the following:

(A) The brand name or corresponding generic name of the drug;

(B) the name of the manufacturer or distributor of the drug, or an easily identified abbreviation of the manufacturer's or distributor's name;

(C) the strength of the drug;

(D) the contents in terms of weight, measure, or numerical count;

(E) the lot number of the drug, if the lot number is not recorded on a suitable log; and

(F) the beyond-use date of the drug.

(3) Prepackaged drugs shall be packaged in suitable containers and shall be subject to all other provisions of the Kansas state board of pharmacy regulations under the uniform controlled substances act of the state of Kansas and under the pharmacy act of the state of Kansas.

(c) The procedures for the control and distribution of drugs within health department facilities and family planning clinics shall be consistent with the following requirements:

(1) Adequate records of the distribution of drugs by the designated registered professional nurse or nurses shall be maintained and shall include the physician's order or written protocol.

(A) If the physician's order was given orally, electronically, or by telephone, the designated registered professional nurse or nurses shall reduce that order to writing. The written copy of the order shall be signed by the designated registered professional nurse and maintained in a permanent patient file.

(B) The records shall include the following:

(i) The full name of the patient;

(ii) the date supplied;

(iii) the name of the drug, the quantity supplied, and strength of the drug distributed;

(iv) the directions for use;

(v) the prescriber's name. The record shall include the name of the practitioner and, if involved, the name of either the physician's assistant (PA) or the advanced registered nurse practitioner (ARNP);

(vi) the expiration date of the drug; and

(vii) the lot number of the drug.

(2) A supply of drugs shall be provided to a patient by a designated registered professional nurse or nurses pursuant to a prescriber's order. Only a designated registered professional nurse or nurses may access the pharmacy area and remove the supply of the drugs. The supply shall conform with the following labeling requirements:

(A) The name, address, and telephone number of the health department or family planning clinic from which the drug is supplied;

(B) the full name of the patient;

(C) adequate directions for use of the drug;

(D) the name of the prescriber. The label shall include the name of the practitioner and, if involved, the name of either the physician's assistant (PA) or the advanced registered nurse practitioner (ARNP);

(E) the date the supply was distributed;

(F) the identification number assigned to the supply of the drug distributed by the health department or family planning clinic;

(G) the brand name or corresponding generic name of the drug;

(H) necessary auxiliary labels and storage instructions, if needed; and

(I) the beyond-use date of the drug issued.

(3) Repackaged drugs shall be packaged in suitable containers and shall be subject to all other provisions of the Kansas state board of pharmacy rules and regulations under the pharmacy act of the state of Kansas.

(d) The appointment of any Kansas licensed pharmacist as pharmacist-in-charge of a health department or family planning clinic shall be subject to the provisions of K.A.R. 68-1-2a and 68-7-13. (Authorized by and implementing K.S.A. 65-1648; effective, T-84-3, Feb. 10, 1983; effective May 1, 1984; amended July 23, 1999; amended April 28, 2000.)

68-7-19. Transfer of a refillable prescription between pharmacies. (a) As used in K.S.A. 65-1656, and amendments thereto, the requested or transferring pharmacy is that pharmacy which has on file the original refillable prescription that the patient wishes to transfer to a second pharmacy. The dispensing or requesting pharmacy is the pharmacy that is wanting the information transferred from the original refillable prescription so that the patient may obtain the medication at this second pharmacy or the pharmacy receiving the transferred prescription.

(b) Valid refillable prescriptions for prescription drugs not listed in schedule II of the uniform controlled substances act may be transferred either by direct communications between two licensed pharmacists from one pharmacy to another pharmacy or by a licensed pharmacist operating a suitable electronic device. Before any prescription is transfered, the prescription information at the transferring pharmacy shall meet all of the following criteria:

(1) The prescription information indicates authorization for refilling by the prescriber.

(2) The drug on the prescription information is not a schedule II controlled substance.

(3) The number of lawfully allowable refills directed by the prescriber has not been exceeded.

(4) The maximum allowable time limit from the original dating of the prescription has not been exceeded.

(c) When a prescription on record is transferred, the following record keeping shall be required:

(1)(A) If the transfer involves a noncontrolled substance, the pharmacist at the transferring pharmacy shall perform the following:

(i) Cancel the transferred prescription by writing the word "void" on its face; and

(ii) record on the face of the prescription the name and address of the pharmacy to which the prescription was transferred, the date of the transfer request, the full name of the pharmacist to which the prescription was transferred, and the full name of the pharmacist transferring the prescription.

(B) If the pharmacy from which the prescription is transferred utilizes a computerized prescription record-keeping system adequate to do so, the transferring pharmacist may record the information required by paragraphs (1)(A)(i) and (ii) in the computer record of the prescription instead of recording the information on the face of the prescription.

(C) Transferring pharmacies that have computerized record-keeping systems that permit requesting pharmacies to electronically transfer prescriptions and prescription information from the

transferring pharmacy to the requesting pharmacy shall establish procedures to permit these transfers only in instances of valid and legal requests and to insure that the prescription information required by subsection (b) is available to the requesting pharmacy at the time of the electronic transfer.

(D) If the requesting pharmacy is transferring a prescription and prescription information from another pharmacy without communicating directly with a pharmacist at the transferring pharmacy, the pharmacist at the requesting pharmacy shall insure that there is a sufficient electronic record left at the transferring pharmacy so that a pharmacist at the transferring pharmacy can comply with the record-keeping requirements of K.S.A. 65-1656, and amendments thereto, and these regulations.

(2)(A) If the transfer involves a C-III, IV, or V controlled substance, the pharmacist at the transferring pharmacy shall perform the following:

(i) Cancel the transferred prescription by writing the word "void" on its face; and

(ii) record on the back of the prescription the name, address, and DEA registration number of the pharmacy to which the prescription was transferred, the date of the transfer request, the full name of the pharmacist to which the prescription was transferred, and the full name of the pharmacist transferring the prescription.

(B) Transferring pharmacies that have computerized prescription record-keeping systems that permit requesting pharmacies to electronically transfer prescriptions and prescription information from the transferring pharmacy to the requesting pharmacy shall establish procedures to permit these transfers only in instances of valid and legal requests and to insure that the prescription information required by subsection (b) is available to the pharmacist at the requesting pharmacy at the time of the electronic transfer.

(C) If the requesting pharmacy is transferring a prescription and prescription information from another pharmacy without communicating directly with a pharmacist at the transferring pharmacy, the pharmacist at the requesting pharmacy shall insure that there is a sufficient electronic record left at the transferring pharmacy so that a pharmacist at the transferring pharmacy can comply with the record-keeping requirements of K.S.A. 65-1656, and amendments thereto, and these regulations.

(3) The prescription record at the pharmacy receiving the transferred prescription shall show the following, in addition to all other lawfully required information of an original prescription:

(A) The word "transfer" written on the face of the prescription record;

(B) the date of original issuance and the date of original filling, if different from the issuance date;

(C) the original number of refills authorized, the number of remaining authorized refills, and the date of last refill;

(D) the original prescription number;

(E) the name, address, and telephone number of the transferring pharmacy, and the name of the transferring pharmacist;

(F) the name, address, and telephone number of the prescriber; and

(G) if the transfer involves a C-III, IV, or V controlled substance, the DEA registration number of the prescriber and of the transferring pharmacy.

(4) If the transfer involves a noncontrolled substance and the pharmacy to which the prescription is transferred utilizes a computerized prescription record-keeping system adequate to do so, the receiving pharmacist may record the information required by paragraphs (3)(A) through (F) in the computer record of the prescription instead of otherwise recording the information.

(d) If two or more pharmacies use common electronic prescription files to maintain dispensing information and do not physically transfer prescriptions or information for dispensing purposes, all pharmacies licensed by the board that have access to these common files shall be responsible to insure that at all times the common files contain at least the following information readily available to any person accessing the file:

(1) Any authorization for refilling by the prescriber;

(2) an indication of whether or not the number of lawfully allowable refills authorized by the prescriber has been exceeded;

(3) an indication of whether or not the maximum allowable time limit from the original date of the prescription has been exceeded;

(4) any other information provided by the original prescription or prescription order; and

(5) the name and address of the pharmacy last dispensing the drug pursuant to the prescription.

(e) The dispensing pharmacy shall advise the patient and notify the transferring pharmacy that

the original prescription shall be canceled in the transferring pharmacy.

(f) A Kansas pharmacist may transfer a valid, refillable prescription from or to another pharmacy in or outside the state of Kansas. Noncontrolled substance prescriptions may be transferred more than once, but C-III, IV, and V controlled substance prescriptions shall not be transferred more than one time. (Authorized by and implementing K.S.A. 1998 Supp. 65-1656; effective March 29, 1993; amended July 23,1999.)

68-7-20. Shared services. (a) (1) "Order" means either of the following:

(A) A prescription order as defined in K.S.A. 65-1626 and amendments thereto; or

(B) a medication order as defined in K.A.R. 68-5-1.

(2) "Shared order filling" means the following:

(A) Preparing, packaging, compounding, or labeling an order, or any combination of these functions, by a person authorized by the pharmacy act to do so and located at a pharmacy on behalf of and at the request of another pharmacy; and

(B) returning the filled order to the requesting pharmacy for delivery to the patient or patient's agent or, at the request of the requesting pharmacy, directly delivering the filled order to the patient.

(3) "Shared order processing" means the following order processing functions that are performed by a person authorized by the pharmacy act and located at a pharmacy, on behalf of and at the request of another pharmacy:

(A) Interpreting and entering the order; and

(B) performing drug utilization reviews, claims adjudication, refill authorizations, or therapeutic interventions, or any combination of these functions.

(4) "Shared services" means shared order filling or shared order processing, or both.

(b) Each pharmacy participating in shared services shall be registered by the board as either a resident or a non-resident pharmacy.

(c) Pharmacies may provide or utilize shared services functions only if the pharmacies involved meet the following requirements:

(1) Share a common electronic file or appropriate technology to allow access to sufficient information necessary to fill, refill, or perform shared services in conformance with the pharmacy act and the board's regulations; and

(2) (A) Have the same owner; or

(B) have a written contract outlining the services provided and the shared responsibilities of each party in complying with the pharmacy act and the board's regulations.

(d) Pharmacies engaged in shared services shall meet the following requirements:

(1) Maintain records identifying, individually for each order processed, the name of each pharmacist, technician, pharmacy student, and intern who took part in the drug utilization review, refill authorization, or therapeutic intervention functions performed at that pharmacy;

(2) maintain records identifying, individually for each order filled or dispensed, the name of each pharmacist, technician, pharmacy student, and intern who took part in the filling, dispensing, and counseling functions performed at that pharmacy;

(3) report to the board as soon as practical the results of any disciplinary action taken by another state's pharmacy board involving shared services;

(4) maintain a mechanism for tracking the order during each step of the processing and filling procedures performed at the pharmacy;

(5) maintain a mechanism to identify on the prescription label all pharmacies involved in filling the order;

(6) provide for adequate security to protect the confidentiality and integrity of patient information; and

(7) be able to obtain for inspection any required record or information within 72 hours of any request by a board representative.

(e) Each pharmacy providing or utilizing shared services shall adopt and maintain a joint policies and procedures manual that meets both of the following criteria:

(1) The manual describes how compliance with the pharmacy act and the board's regulations will be accomplished while engaging in shared services.

(2) A copy of the manual is maintained in each pharmacy.

(f) Nothing in this regulation shall prohibit an individual pharmacist licensed in Kansas who is an employee of or under contract with the pharmacy from accessing the pharmacy's electronic database from inside or outside the pharmacy and performing the order processing functions permitted by the pharmacy act, if both of the following conditions are met:

(1) The pharmacy establishes controls to protect the privacy and security of confidential records.

(2) None of the database is duplicated, downloaded, or removed from the pharmacy's electronic database. (Authorized by K.S.A. 65-1630 and K.S.A. 65-1656; implementing K.S.A. 2006 Supp. 65-1626(cc), as amended by L. 2007, ch. 177, sec. 30 and L. 2007, ch. 195, sec. 34, K.S.A. 65-1626a, K.S.A. 2006 Supp. 65-1637, as amended by L. 2007, ch. 19, sec. 1, K.S.A. 2006 Supp. 65-1642, and K.S.A. 65-1656; effective April 16, 2004; amended April 18, 2008.)

Article 8.—ADVERTISING

68-8-1. Advertising. Licensees, registrants, and permit holders shall not use or allow to be used for their benefit any advertising that is false or misleading. (Authorized by and implementing K.S.A. 65-1630; implementing K.S.A. 65-1650; modified, L. 1978, ch. 466, May 1, 1978; amended May 1, 1985; amended May 1, 1988; amended April 18, 2003.)

Article 9.—AUTOMATED PRESCRIPTION SYSTEMS

68-9-1. Electronic data storage systems. All electronic data storage systems operating within this state shall comply with the following requirements:

(a) The pharmacist in charge of such a system shall perform the following:

(1) Adopt a written policy and procedures manual for control, use, and operation of the system;

(2) assure that only licensed pharmacists make decisions concerning judgmental functions as stated in K.A.R. 68-2-20;

(3) be responsible for all drug information within the system;

(4) assure that complete control over the dispensing of medication is vested in licensed pharmacists;

(5) have an auxiliary procedure that shall be used for documentation of refills of all prescription orders if the system becomes inoperable. This auxiliary procedure shall insure that the following criteria are met:

(A) Refills are authorized by the original prescription order;

(B) the maximum number of refills has not been exceeded; and

(C) a daily backup is performed for use in restoring required information in case of a system failure;

(6) maintain a written prescription on file that preserves all information contained in the original prescription. A machine-printed supplement that provides all information necessary to comply with the law may be filed with or attached to the written prescription, if the supplement does not obscure the required information on the original prescription;

(7) provide a method of numerically identifying each patient's written prescription;

(8) maintain the confidentiality of prescriptions and assure that the system has adequate security and systems safeguards to prevent unauthorized access, modification, or manipulation of patient medication profile data; and

(9) maintain a written or electronic prescription daily log. The daily log shall include the following information:

(A) The original prescription number;

(B) the date of the issuance of the original prescription order by the practitioner;

(C) the full name and address of the patient;

(D) the name and address of the practitioner;

(E) the practitioner's DEA registration number if required;

(F) the name, strength, dosage form, and quantity of the medication prescribed;

(G) the quantity dispensed, if different from the quantity prescribed; and

(H) the total number of refills authorized by the prescribing practitioner.

(b) Each electronic data storage system shall have a method for each of the following:

(1) Storing each active patient's medication profile record so that this record is immediately available upon request at the practice site. Sufficient historical patient medication profile data shall be stored and made available for the pharmacist to exercise appropriate clinical judgment when dispensing the prescription;

(2) documenting that an individual pharmacist has taken responsibility for the accuracy of the following:

(A) The information entered; and

(B) Each authorized refilling of the prescription;

(3) drug use control, which shall include the following:

(A) The ability to ascertain quantities;

(B) the exact refill data;

(C) the dates of previous refillings; and

(D) the number of refills remaining;

(4) identifying on a daily basis the pharmacist filling each prescription;

(5) handling partial fillings and refillings of prescriptions;

(6) handling compounded prescriptions;

(7) reproducing all information within the system, in written form and upon authorized request, within 72 hours; and

(8) providing a label containing the information required under K.A.R. 68-7-14 and the date of the original filling of any scheduled drugs. (Authorized by K.S.A. 65-1630 and K.S.A. 2001 Supp. 65-4102; implementing K.S.A. 2001 Supp. 65-1626(t), K.S.A. 2001 Supp. 65-1642, and K.S.A. 65-4121; effective May 1, 1980; amended May 1, 1989; amended April 3, 1990; amended Sept. 9, 1991; amended March 22, 2002.)

68-9-2. Automated drug delivery systems. (a) For purposes of this regulation, "automated drug delivery system" shall include any mechanical system that performs operations or activities other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs, in situations in which the drug is not reviewed by a Kansas-licensed pharmacist after it leaves the mechanical system and before it is dispensed, distributed, or administered.

(b) A pharmacist-in-charge of any licensed pharmacy, licensed health care facility, or other location that is required to be supervised by a pharmacist-in-charge and that uses an automated drug delivery system shall be responsible to take the following steps before allowing the automated drug delivery system to be used:

(1) Ensure that the automated drug delivery system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards;

(2) ensure that the automated pharmacy system has a mechanism for securing and accounting for drugs removed from and subsequently returned to the system;

(3) ensure that the automated pharmacy system has a mechanism for securing and accounting for wasted or discarded drugs;

(4) implement a documented and ongoing quality assurance program that monitors total system performance and includes the requirement for accuracy in the drug and strength delivered;

(5) ensure that the automated drug delivery system is stocked accurately and according to established and written policies and procedures;

(6) ensure that the use of the automated drug delivery system maintains patient confidentiality;

(7) approve and implement an operational policy that limits the personnel responsible for the loading and unloading of the automated drug delivery system to a Kansas-licensed pharmacist or to any of the following, each of whom shall be under the pharmacist's direct supervision:

(A) A pharmacy student;

(B) a pharmacy intern; or

(C) a pharmacy technician;

(8) approve and implement security measures that comply with state and federal laws and regulations in order to prevent unauthorized individuals from accessing or obtaining drugs;

(9) preapprove all individuals who are authorized to remove any drug and maintain, at the location of the automated drug delivery system, a list of those approved individuals;

(10) ensure the accuracy of the automated drug delivery system's collection, control, and maintenance of all transaction information needed to track the movement of drugs into and out of the system for security, accuracy, and accountability; and

(11) provide the board with prior written notice of the installation or removal of the automated drug delivery system.

(c) A pharmacist-in-charge of any licensed pharmacy, licensed health care facility, or other location that is required to be supervised by a pharmacist-in-charge and that uses an automated drug delivery system shall be responsible to ensure all of the following:

(1)The drugs within the automated drug delivery system are inspected on-site by a Kansas-licensed pharmacist or by any of the following, each of whom shall be under the pharmacist's direct supervision:

(A) A pharmacy student;

(B) a pharmacy intern; or

(C) a pharmacy technician. These inspections shall be conducted at least monthly to ensure accuracy of contents.

(2) All drugs placed within the device are packaged in the manufacturer's sealed original packaging or in repackaged containers, in compliance with the requirements of K.A.R. 68-7-15 and K.A.R. 68-7-16. However, the dispensing container shall not be required to be labeled as spec-

ified in K.A.R. 68-7-14 if the dispensing container is utilized for a registered patient of the licensed health care facility and for immediate administration.

(3) At the time of loading any controlled substance, the count of that drug in the automated drug delivery system is correct, or any discrepancy is immediately reported to the pharmacist-in-charge, who shall be responsible for reconciliation of the discrepancy or proper reporting of the loss. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 Supp. 65-1626, as amended by L. 2002, ch. 25, sec. 2; effective July 6, 2001; amended Feb. 7, 2003.)

Article 10.—NUCLEAR PHARMACY

68-10-1 to 68-10-3. Not in active use.

Editor's Note:
Proposed regulations 68-10-1 to 68-10-3, rejected by legislature, see L. 1983, ch. 356.

Article 11.—FEES

68-11-1. Fees for examination and licensure as a pharmacist. The following fees shall be paid to the board by each applicant for examination and licensure as a pharmacist:

(a) Each applicant for examination shall pay a fee of $50.00 to the Kansas board of pharmacy.

(b) Each applicant for reciprocal licensure shall pay a fee of $80.00 to the Kansas board of pharmacy.

(c) An additional fee of $250.00 to evaluate the education and training shall be paid by each applicant for reciprocal licensure or examination who graduated from a school or college of pharmacy or department of a university not approved by the board.

(d) Each licensed pharmacist shall pay a renewal fee of $150.00.

(e) The penalty fee for a late renewal of a pharmacist license shall be $200.00.

(f) The fee for a new or renewed pharmacist license shall be prorated to the nearest whole month for any period of time consisting of fewer than two years. (Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1645; effective May 1, 1983; amended May 1, 1986; amended May 1, 1987; amended May 1, 1988; amended May 1, 1991; amended Nov. 30, 1992; amended June 6, 1994; amended July 31, 1998; amended Feb. 5, 1999; amended Feb. 7, 2003; amended Oct. 20, 2006.)

68-11-2. Fees for premises registrations and permits. (a) Pharmacy registration fees shall be as follows:

(1) Each new pharmacy registration shall be $140.00.

(2) Each renewal pharmacy registration shall be $125.00.

(b) Manufacturer registration fees shall be as follows:

(1) Each new manufacturer registration shall be $300.00.

(2) Each renewal manufacturer registration shall be $300.00.

(c) Wholesaler distributor registration fees shall be as follows:

(1) Each new wholesaler distributor registration shall be $300.00.

(2) Each renewal wholesaler distributor registration shall be $300.00.

(3) For each wholesaler who deals exclusively in nonprescription drugs, the registration fee shall be $50.00.

(d) For each institutional drug room or veterinary medical teaching hospital pharmacy, registration fees shall be as follows:

(1) Each new registration shall be $25.00.

(2) Each renewal registration shall be $20.00.

(e) Other permit fees shall be as follows:

(1) Each retail dealer permit shall be $12.00.

(2) Each auction permit shall be $35.00.

(3) Each sample distribution permit shall be $30.00.

(f) For each place of business that sells durable medical equipment, the registration fee shall be $300.00. (Authorized by and implementing K.S.A. 2007 Supp. 65-1645; effective May 1, 1983; amended May 1, 1988; amended June 6, 1994; amended Feb. 7, 2003; amended Oct. 24, 2008.)

Article 12.—RESALE OF MEDICATION

68-12-1. Not in active use.

Editor's Note:
Proposed regulation 68-12-1, rejected by legislature, see L. 1983, ch. 356.

68-12-2. Resale of dispensed prescription drugs. Except for prescription drugs in unit-dose systems that contain only one medication and in which the drug has not reached the patient and is still intact, prescription drugs that have been dispensed to the final consumer shall not be resold, redispensed, or distributed by a licensed pharmacist. (Authorized by K.S.A. 65-1630; im-

plementing K.S.A. 65-1634; effective May 1, 1988; amended Nov. 30, 1992; amended, T-68-11-19-92, Nov. 30, 1992; amended March 29, 1993; amended Feb. 7, 2003.)

Articles 13.—PARENTERAL PRODUCTS

68-13-1. Preparation, compounding, and dispensing of parenteral products for other than immediate use. (a) Each pharmacist engaged in the preparation and compounding of sterile parenteral products shall have available the following resources:

(1) A laminar airflow hood or other suitable aseptic environment that is annually certified to ensure aseptic conditions within the working area of the pharmacy;

(2) an aseptic work area that is designed to avoid outside traffic and outside airflow and that is ventilated so that the traffic and outside airflow do not interfere with aseptic conditions. The aseptic work area shall not be used for bulk storage of supplies or other materials;

(3) a sink located nearby that is suitable for cleaning purposes;

(4) a current copy of a reference text in intravenous incompatibilities and stabilities, or access to such a reference text in electronic format;

(5) a current policy and procedure manual that includes the following subjects:

(A) Sanitation;

(B) storage;

(C) dispensing;

(D) labeling;

(E) destruction and returns;

(F) recordkeeping;

(G) recall procedures;

(H) responsibilities and duties of supportive personnel; and

(I) aseptic compounding techniques.

(b) All sterile parenteral products for other than immediate use shall be prepared under aseptic conditions and shall be stored and shipped in a manner that ensures parenteral product stability.

(1) Preparation of insulin mixtures shall be made in an aseptic environment where available.

(2) Cancer chemotherapeutic agents shall be prepared in a vertical airflow aseptic environment where available. These agents shall not be prepared in a horizontal airflow hood.

(c) Before dispensing sterile parenteral products for use, the pharmacist-in-charge shall verify that the following programs or services are contemporaneously available or have been provided:

(1) 24-hour emergency services;

(2) monitoring of clinical laboratory data as needed;

(3) documentation and reporting of potential drug interactions and side effects to the prescribing practitioner;

(4) maintenance of patient histories and therapy plans; and

(5) education and training of the patient or primary caregiver.

(d) Each pharmacist engaged in the dispensing of parenteral products shall conform to all labeling requirements under state and federal law. In addition, parenteral product labels shall bear the following information:

(1) The name and quantity of each drug and additive;

(2) the expiration date;

(3) the prescribed flow rate; and

(4) the storage instructions, if applicable. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 Supp. 65-1642; effective May 1, 1988; amended Feb. 7, 2003.)

Article 14.—WHOLESALE DISTRIBUTORS

68-14-1. Wholesale distributors. "Wholesale distributor" means any person, partnership, corporation, or business firm licensed or registered in this state and engaging in the wholesale distribution of prescription-only drugs. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1998 Supp. 65-1643; effective June 15, 1992; amended March 20, 1995; amended July 30, 1999.)

68-14-2. Definitions. (a) "Blood" means whole blood collected from a single donor and processed either for transfusion or for further manufacturing.

(b) "Blood component" means that part of blood separated by physical or mechanical means.

(c) "Common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.

(d) "Drug sample" means a unit of a prescription-only drug that is not intended to be sold, is intended to promote the sale of the drug, and is distributed on a gratuitous basis.

(e) "Emergency medical reasons" include transfers of prescription-only drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of these transfers shall not exceed five percent of the total prescription-only drug sales revenue of either the transferor or transferee pharmacy during any period of 12 consecutive months.

(f) "Intracompany sales" means any transaction or transfer between any division, subsidiary, parent, affiliated, or related company under the common ownership and control of a corporate entity.

(g) "Primary owner" means any person owning or controlling more than 50 percent of the wholesaler's business.

(h) "Wholesale distribution" means distribution of prescription-only drugs to persons other than a consumer or patient, but this term shall not include any of the following:

(1) Intracompany sales;

(2) the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of these organizations;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the U.S. internal revenue code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

(5) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

(6) the sale, purchase, or trade of a drug; an offer to sell, purchase, or trade a drug; or the dispensing of a drug pursuant to a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) the sale, purchase, or trade of blood and blood components intended for transfusion.

(i) "Wholesale distributor" means anyone doing business in this state and engaging in wholesale distribution of prescription-only drugs, including the following:

(1) Manufacturers;

(2) repackers;

(3) own-label distributors;

(4) private-label distributors;

(5) jobbers;

(6) brokers;

(7) warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;

(8) independent wholesale drug traders; and

(9) retail pharmacies that conduct wholesale distributions. (Authorized by and implementing K.S.A. 65-1630; effective June 15, 1992; amended July 23, 1999.)

68-14-3. Wholesale distributor registration requirement. Every wholesale distributor doing business in this state who engages in wholesale distributions of prescription-only drugs shall be registered by the board, in accordance with the laws of the pharmacy act and regulations, before engaging in wholesale distributions of prescription-only drugs. (Authorized by and implementing K.S.A. 1998 Supp. 65-1655 and 65-1643; effective June 15, 1992; amended July 23, 1999.)

68-14-4. Minimum required information for registration. (a) Each wholesale distributor shall provide the board with the following minimum information as part of the registration requirements described in K.S.A. 65-1645, and amendments thereto, and as part of any renewal of any registration:

(1) The name, full business address, and telephone number of the registrant;

(2) each trade or business name used by the registrant;

(3) the address, telephone number, and name of the contact person for each facility used by the registrant for the storage, handling, and distribution of prescription-only drugs;

(4) the type of ownership or operation, including partnership, corporation, or sole proprietorship; and

(5) the name of each owner, operator, or both, of the registrant, including the following:

(A) If a person, the name of the person;

(B) if a partnership, the name of each partner, and the name of the partnership;

(C) if a corporation, the name and title of each corporate officer and director, the corporate name, and the name of the state of incorporation; and

(D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(b) A single registration may be issued by the board for any business entity operating more than one facility within this state, or for a parent entity with divisions, subsidiaries, affiliate companies, or some combination of these within this state when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(c) Each registrant shall submit revised information requested by subsection (a) within 30 days after any change in that information. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1998 Supp. 65-1645 and 65-1655; effective June 15, 1992; amended July 23, 1999.)

68-14-5. Personnel. As a condition for receiving and retaining a wholesale distributor registration, the registrant shall require each person employed in any prescription-only drug wholesale distribution activity to have education, training, and experience, or any combination of these, sufficient for that person to perform the assigned functions in a manner providing assurance that the drug product quality, safety, and security will at all times be maintained as required by law. (Authorized by and implementing K.S.A. 1998 Supp. 65-1655; effective June 15, 1992; amended July 23, 1999.)

68-14-6. Violations and penalties. Any license or registration granted under this article may be suspended or revoked by the board for willful and serious violation of these regulations. (Authorized by and implementing K.S.A. 1991 Supp. 65-1655; effective June 15, 1992.)

68-14-7. Minimum requirements for the storage and handling of prescription-only drugs and for the establishment and maintenance of prescription-only drug distribution records. Each registrant shall meet the following minimum requirements for the storage and handling of prescription-only drugs, and for the establishment and maintenance of prescription-only drug distribution records by wholesale distributors and their officers, agents, representatives, and employees.

(a) Facilities. Each facility at which prescription-only drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall meet the following requirements:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) have a quarantine area for storage of prescription-only drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(4) be maintained in a clean and orderly condition; and

(5) be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security.

(1) Each facility used for wholesale drug distribution shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well controlled.

(B) The outside perimeter of the premises shall be well lighted.

(C) Entry into areas where prescription-only drugs are held shall be limited to authorized personnel.

(2) Each facility shall be equipped with an alarm system to detect entry after hours.

(3) Each facility shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage. All prescription-only drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of these drugs, or with requirements in the 1995 edition of the United States pharmacopeia/national formulary (USP/NF), which is adopted by reference.

(1) If no storage requirements are established for a prescription-only drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity-recording equipment, devices, logs, or a combination of these methods shall be utilized to document proper storage of prescription-only drugs.

(3) The record-keeping requirements in subsection (f) of this regulation shall be followed for all stored drugs.

(d) Examination of materials.

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription-only drugs or prescription-only drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription-only drug products and to ensure that there is no delivery of prescription-only drugs that have been damaged in storage or held under improper conditions.

(3) The record-keeping requirements in subsection (f) of this regulation shall be followed for all incoming and outgoing prescription-only drugs.

(e) Returned, damaged, and outdated prescription-only drugs.

(1) Prescription-only drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription-only drugs until they are destroyed or returned to their supplier.

(2) Any prescription-only drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription-only drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription-only drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigations prove that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether or not the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other factors, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The record-keeping requirements in subsection (f) of this regulation shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription-only drugs.

(f) Record keeping.

(1) Each wholesale distributor shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription-only drugs. These records shall include the following information:

(A) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(B) the identity and quantity of the drugs received and either distributed or disposed of; and

(C) the dates of receipt and either distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for five years following disposition of the drugs.

(3) Records described in this regulation that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(g) Written policies and procedures. Each wholesale distributor shall establish, maintain, and adhere to written policies and procedures concerning the receipt, security, storage, inventory, and distribution of prescription-only drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, each wholesale distributor shall establish, maintain, and adhere to the following written policies and procedures:

(1) a procedure by which the oldest approved stock of a prescription-only drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate;

(2) a procedure to be followed for handling recalls and withdrawals of prescription-only drugs. This procedure shall be adequate to deal with recalls and withdrawals due to any of the following:

(A) Any action initiated at the request of the food and drug administration or other federal,

state, or local law enforcement or other government agency, including the board;

(B) any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(C) any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(3) a procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency; and

(4) a procedure to ensure that any outdated prescription-only drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription-only drugs. This documentation shall be maintained for five years after disposition of the outdated drugs.

(h) Responsible persons. Each wholesale distributor shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale prescription-only drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(i) Compliance with federal, state, and local law. Each wholesale distributor that deals in controlled substances shall register with the drug enforcement administration.

Each wholesale distributor shall permit the board's authorized personnel and authorized federal, state, and local law enforcement officials to enter and inspect the distributor's premises and delivery vehicles, and to audit the records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. These officials shall be required to show appropriate identification before being permitted access to wholesale distributors' premises and delivery vehicles.

(j) Salvaging and reprocessing. Each wholesale distributor shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription-only drug product salvaging or reprocessing. (Authorized by K.S.A. 65-1630 and implementing K.S.A. 65-1634; effective June 15, 1992; amended July 23, 1999.)

68-14-8. Wholesale distributors transaction. (a) Notwithstanding any other provision of these regulations under article 14, a wholesale distributor, duly registered with the board, may sell or deliver to a layperson responsible for the control of an animal, a prescription-only drug to be administered to the animal only if a licensed veterinarian practitioner has issued, before the sale or delivery, a lawful written prescription or order for the prescription-only drug in the course of an existing, valid veterinarian-client-patient relationship as defined in K.S.A. 47-816 and amendments thereto. As used in these regulations under article 14, "wholesale distribution" shall include this transaction.

(1) Except as otherwise provided in this regulation, at the time the prescription-only drug leaves the registered location of the wholesale distributor, the wholesale distributor shall possess, at the registered location, a copy of the written prescription or order for the drug.

(2) Except as otherwise provided in this regulation, at the time the prescription-only drug is delivered to the layperson, the person making the delivery shall possess a copy of the written prescription or order for the drug.

(3) The wholesale distributor shall retain, for a period of five years, a copy of the written prescription or order in a manner that makes it readily available for review by a board representative.

(b) In lieu of receiving a written prescription or order from a licensed veterinarian practitioner before a prescription-only drug leaves the registered location, the wholesale distributor may accept a verbal order from a licensed veterinarian practitioner if all of the following conditions are met:

(1) The licensed veterinarian practitioner has created a written prescription or order, but advised the wholesale distributor that, under the circumstances, it is not reasonably possible for the licensed veterinarian practitioner to provide the written prescription or order to the wholesale distributor before the prescription-only drug leaves the registered location.

(2) The licensed veterinarian practitioner provides to the wholesale distributor all of the information required by K.A.R. 70-7-1(n) to be included in a written order for a prescription of legend drugs.

(3) The verbal order is received in a communication directly with the licensed veterinarian practitioner.

(4) The wholesale distributor makes, at the time the verbal order is received, a written confirmation of the information provided by the licensed veterinarian practitioner and records the following information:

(A) The name of the licensed veterinarian practitioner;

(B) the date and time the verbal order was received; and

(C) the name of the person making the written confirmation.

(5) At the time of receiving the verbal order, the wholesale distributor requests that the licensed veterinarian practitioner send a written prescription for the prescription-only drugs so that it is received by the wholesale distributor within 72 hours of receipt of the verbal order and, if it is not received, advises the Kansas board of veterinary examiners of this in writing.

(6) At the time the prescription-only drug leaves the registered location of the wholesale distributor, the wholesale distributor possesses, at the registered location, the original written confirmation.

(7) At the time the prescription-only drug is delivered to the layperson responsible for the control of the animal, the person making the delivery possesses a copy of the written confirmation.

(8) The original written confirmation is maintained by the wholesale distributor for five years in a manner that makes it readily available for review by a board representative. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1999 Supp. 65-1635(d); effective July 23, 1999; amended Nov. 27, 2000.)

Article 15.—NONPRESCRIPTION WHOLESALE DISTRIBUTORS

68-15-1. Nonprescription wholesale distributors. "Nonprescription wholesale distributor" shall mean any person, partnership, corporation, or business firm registered in this state and engaging in the distribution of drugs that are not prescription-only drugs to persons or entities other than a consumer or patient. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1998 Supp. 65-1643(c); effective July 23, 1999.)

68-15-2. Nonprescription wholesale distributor registration required. A nonprescription wholesale distributor may engage in the distribution of nonprescription drugs to persons or entities, other than a consumer or patient in Kansas, if both of the following conditions are met:

(a) The drugs are prepackaged, fully prepared by the manufacturer or distributor for use by a consumer, and appropriately labeled.

(b) The distributor has first obtained a registration to do so from the board. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1998 Supp. 65-1643(c) and K.S.A. 65-1634; effective Sept. 24, 1999.)

68-15-4. Minimum requirements for storage. All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with any requirements in the labeling or packaging of the drugs, or with any requirements in the United States pharmacopeia: the national formulary (USP/NF), as in effect on March 15, 1999 and published January 1, 1995. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1998 Supp. 65-1643(c) and K.S.A. 65-1634; effective Sept. 24, 1999.)

Article 16.—CANCER DRUG REPOSITORY PROGRAM

68-16-1. Definitions. As used in these regulations for the cancer drug repository program, the following terms shall have the meanings specified:

(a) "Board" means the Kansas state board of pharmacy.

(b) "Cancer drug" has the meaning specified in K.S.A. 65-1664 and amendments thereto. For the purposes of this article, "drug" shall mean "cancer drug."

(c) "Cancer drug repository" means a hospital, nonprofit clinic, physician's office, or pharmacy that has notified the board of its election to participate in the cancer drug repository program.

(d) "Cancer drug repository donor form" means the cancer drug repository form provided by the board.

(e) "Cancer drug repository receipt form" means the cancer drug repository receipt form provided by the board.

(f) "Dispense" has the meaning specified in K.S.A. 65-1626(h) and amendments thereto.

(g) "Dispensing physician" has the meaning specified in K.A.R. 100-21-1.

(h) "Distribute" has the meaning specified in K.S.A. 65-1626(j) and amendments thereto.

(i) "Distributor" has the meaning specified in K.S.A. 65-1626(k) and amendments thereto.

(j) "Hospital" has the meaning specified in K.S.A. 65-425 and amendments thereto.

(k) "Manufacture" has the meaning specified in K.S.A. 65-1626(q) and amendments thereto.

(l) "Nonprofit clinic" has the meaning specified in K.S.A. 65-1664(a)(3) and amendments thereto.

(m) "Original sealed," when used to describe a cancer drug container, means that the container has been originally sealed by the manufacturer or a pharmacy.

(n) "Pharmacist" has the meaning specified in K.S.A. 65-1626(s) and amendments thereto.

(o) "Pharmacy" has the meaning specified in K.S.A. 65-1626(u) and amendments thereto.

(p) "Practitioner" means a person licensed to practice medicine or surgery by the Kansas state board of healing arts.

(q) "Prescription medication" has the meaning specified in K.S.A. 65-1626(aa) and amendments thereto.

(r) "Side effects of cancer" means the symptoms of cancer.

(s) "Single-unit-dose packaging" means a single-unit container for a drug intended for administration as a single dose, direct from the container.

(t) "Tamper-evident unit-dose packaging" means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal. (Authorized by and implementing K.S.A. 2005 Supp. 65-1667; effective Dec. 1, 2006.)

68-16-2. Requirements for participation by physicians, pharmacies, hospitals and nonprofit clinics. Each physician, pharmacy, hospital, and nonprofit clinic that elects to participate in the cancer drug repository program shall provide written notification of the following to the board:

(a) The name, street address, and telephone number of the participating physician, pharmacy, hospital, or nonprofit clinic;

(b) the name and telephone number of a contact person employed by the physician, pharmacy, hospital, or nonprofit clinic; and

(c) a statement specifying whether the physician, pharmacy, hospital, or nonprofit clinic will be dispensing donated cancer drugs. (Authorized by and implementing K.S.A. 2005 Supp. 65-1667; effective Dec. 1, 2006.)

68-16-3. Donation of cancer drugs. (a) Only a cancer drug that meets the following conditions may be accepted:

(1) The drug has not been compounded.

(2) The drug has not been previously dispensed from a cancer drug repository.

(3) The drug's packaging includes the drug's lot number and expiration date. If the drug is repackaged, the expiration date shall be one year from the date of repackaging or from the expiration date established when the drug was dispensed before donation, whichever is sooner. Single-unit-dose drugs may be accepted if the single-unit-dose packaging is unopened.

(b) Any cancer drug may be accepted only if the donor simultaneously provides the cancer drug repository with a completed cancer drug repository donor form signed by the person making the donation.

(c) A cancer drug repository shall not accept the donation of any controlled substance.

(d) Each cancer drug repository shall receive donated drugs only at the premises of that cancer drug repository and only by an individual authorized by the repository to receive donated cancer drugs. A drop box shall not be used to deliver or accept donations.

(e) Each cancer drug donated under the cancer drug repository program shall be stored in a secure storage area under environmental conditions appropriate for the drugs being stored. All donated drugs shall be stored separately from and not commingled with drugs that are not donated. (Authorized by and implementing K.S.A. 2005 Supp. 65-1667; effective Dec. 1, 2006.)

68-16-4. Dispensing requirements. (a) Before dispensing any donated cancer drug, each pharmacist or dispensing physician shall inspect the cancer drug to determine that the original unit-dose packaging is sealed and tamper-evident and to check for adulteration, misbranding, and the expiration date. A cancer drug shall not be dispensed if any of the following conditions is met:

(1) The original unit-dose packaging is not sealed and tamper-evident.

(2) The drug is adulterated or misbranded.

(3) The drug's expiration date has passed.

(b) Before any donated cancer drug is dispensed, it shall be labeled to identify it as a medication dispensed from a cancer drug repository.

(c) Each cancer drug shall be dispensed only to a cancer patient.

(d) When any cancer drug is dispensed, the re-

cipient shall be orally notified that the drug might have been previously dispensed.

(e) Before a cancer drug may be dispensed to a recipient, the recipient shall sign a cancer drug repository receipt form, which shall include an acknowledgment that the recipient was orally notified that the drug might have been previously dispensed.

(f) A donated cancer drug may be removed from a unit-dose package and dispensed in a vial if the pharmacist or dispensing physician determines that doing so is in the best interest of the patient. Only a pharmacist, pharmacy technician, pharmacy student, or dispensing physician may remove a cancer drug from a unit-dose package and repackage the drug.

(g) Any donated cancer drug may be dispensed no more than one time after being donated. (Authorized by and implementing K.S.A. 2005 Supp. 65-1667; effective Dec. 1, 2006.)

68-16-5. Handling fees. Any cancer drug repository may charge the recipient a handling fee of no more than 300 percent of the medicaid dispensing fee or $15.00, whichever is less, for each cancer drug dispensed. (Authorized by and implementing K.S.A. 2005 Supp. 65-1665 and K.S.A. 2005 Supp. 65-1667; effective Dec. 1, 2006.)

68-16-6. Distribution of donated cancer drugs. (a) Any cancer drug repository may distribute drugs donated under the cancer drug repository program to another cancer drug repository if requested by that cancer drug repository.

(b) When a cancer drug repository distributes a drug to another participating cancer drug repository, the distributing repository shall complete a cancer drug repository donor form. The form completed by the distributing repository and a copy of the cancer drug repository donor form that was completed by the original donor shall be provided to the receiving cancer drug repository at the time of distribution.

(c) Each distributing repository shall maintain, for at least five years, a copy of the forms provided to the receiving drug repository at the time of distribution. (Authorized by and implementing K.S.A. 2005 Supp. 65-1667; effective Dec. 1, 2006.)

68-16-7. Sale of donated drugs. Donated drugs shall not be sold. The sale of donated drugs may result in the following: (a) The loss of the ability to participate in the cancer drug repository program; and

(b) any other penalties that may be imposed pursuant to the Kansas pharmacy act. (Authorized by and implementing K.S.A. 2005 Supp. 65-1667; effective Dec. 1, 2006.)

68-16-8. Recordkeeping requirements. (a) All cancer drug repository donor forms and cancer drug repository receipt forms shall be maintained for at least five years. The original donor form shall remain with the drug until it is dispensed to a patient.

(b) Each cancer drug repository that destroys any donated cancer drug shall create a written record of the destruction that contains the following information and shall maintain the record for at least five years:

(1) The date on which the cancer drug was destroyed;

(2) the name, strength, and quantity of the cancer drug destroyed;

(3) the name of the person or entity that destroyed the cancer drug; and

(4) the name of the person or entity from which the cancer drug was received. (Authorized by and implementing K.S.A. 2005 Supp. 65-1667; effective Dec. 1, 2006.)

68-16-9. Forms. (a) Each cancer drug repository receipt form shall contain at least the following:

(1) The name and quantity of each drug received;

(2) a statement that the individual receiving the drug is aware of the criminal and civil immunity provisions contained in K.S.A. 65-1666 and amendments thereto; and

(3) the dated signature of the individual receiving the drug.

(b) Each cancer drug repository donor form shall contain at least the following:

(1) A space in which the donor shall describe the donor's relationship to the person to whom the drug was originally dispensed and the manner in which the drug came into the donor's possession; and

(2) the dated signature of the donor. (Authorized by and implementing K.S.A. 2005 Supp. 65-1667; effective Dec. 1, 2006.)

Article 17.—RESERVED

Article 18.—UTILIZATION OF UNUSED MEDICATIONS

68-18-1. Transferring unused medications. (a) Each administrator or operator of an

adult care home, pharmacist-in-charge of a mail service pharmacy, and administrator of a medical care facility who wants to become a donating entity, as defined in L. 2008, ch. 9, sec. 2 and amendments thereto, shall submit to the board written notification of intent to participate in the unused medications program. The notification shall be submitted on a form approved by the board.

(b) Before the transfer of each unused medication to a qualifying center or clinic, each mail service pharmacy and medical care facility that has become a donating entity as specified in subsection (a) shall perform the following:

(1) Determine the quality and suitability of each unused medication by a pharmacist's verification that the unused medication meets the following requirements:

(A) Can be identified;

(B) is in the manufacturer's sealed container, a pharmacy unit-dose package, or a hermetically sealed tamper-evident package from the pharmacy;

(C) has not passed its beyond-use date;

(D) is not a controlled substance;

(E) has not been adulterated; and

(F) is not a medication that can be dispensed only to a patient or resident registered with the drug manufacturer;

(2) remove the name of the patient or resident and all of the patient's or resident's personal identifiers in order to protect confidentiality;

(3) consult with the qualifying center or clinic to determine whether the qualifying center or clinic is willing to accept each unused medication; and

(4) ensure that the qualifying center or clinic has a consulting pharmacist and is registered with the board to accept unused medications.

(c) Before the transfer of each unused medication to a qualifying center or clinic, each adult care home that has become a donating entity as specified in subsection (a) shall meet the requirements specified in paragraphs (b)(2), (3), and (4).

(d) When a donating entity transfers an unused medication to a qualifying center or clinic, the donating entity shall meet the following requirements:

(1) Complete a manifest on a form approved by the board; and

(2) include a copy of the manifest with the unused medications.

(e) Each donating entity shall maintain a copy of the manifest that the donating entity provided to the qualifying center or clinic for at least five years. The donating entity shall also maintain a copy of the manifest that was signed and returned by the qualifying center or clinic for at least five years.

(f) A donating entity shall not transfer an unused medication that can be dispensed only to a patient or resident registered with the drug manufacturer. (Authorized by and implementing L. 2008, ch. 9, §7; effective Jan. 2, 2009.)

68-18-2. Accepting unused medications. (a) Each qualifying center or clinic that elects to participate in the unused medications program shall submit to the board written notification of intent to participate on a form approved by the board.

(b) Each qualifying center or clinic shall maintain all unused medications in a storage unit with controlled access.

(c) After the acceptance of each unused medication from an adult care home that has become a donating entity as specified in K.A.R. 68-18-1(a), each qualifying center or clinic shall perform the following:

(1) Determine the quality and suitability of each unused medication by verification of a pharmacist that the unused medication meets the following requirements, in addition to the requirements of L. 2008, ch. 9, sec. 4 and amendments thereto:

(A) Can be identified; and

(B) is not a medication that can be dispensed only to a patient or resident registered with the drug manufacturer;

(2) ensure that the name of the patient or resident and all of the patient's or resident's personal identifiers have been removed in order to protect confidentiality;

(3) check each unused medication against the manifest to resolve any discrepancies with the donating entity; and

(4) complete the manifest and return a copy of the manifest to the donating entity.

(d) After the acceptance of each unused medication from a mail service pharmacy or a medical care facility that has become a donating entity as specified in K.A.R. 68-18-1(a), each qualifying center or clinic shall perform the following:

(1) Determine the quality and suitability of each unused medication by the verification of a pharmacist or practitioner that the unused medication meets the following requirements, in addition to

the requirements of L. 2008, ch. 9, sec. 4 and amendments thereto:

(A) Can be identified; and

(B) is not a medication that can be dispensed only to a patient or resident registered with the drug manufacturer; and

(2) meet all of the requirements specified in paragraphs (c)(2), (3), and (4).

(e) Each qualifying center or clinic shall maintain a copy of the manifest that was provided by the donating entity for at least five years. The qualifying center or clinic shall also maintain a copy of the manifest signed and returned to the donating agency for at least five years.

(f) A qualifying center or clinic shall not accept or dispense an unused medication that can be dispensed only to a patient or resident registered with the drug manufacturer. (Authorized by and implementing L. 2008, ch. 9, §7; effective Jan. 2, 2009.)

68-18-3. Recall of unused medications. (a) If an unused medication is recalled and the qualifying center or clinic does not have the lot number on the label to differentiate between the recalled medications and the nonrecalled medications, all of the unused medications shall be destroyed.

(b) If a donating entity has transferred an unused medication to a qualifying center or clinic, the medication is subsequently recalled, and the donating entity has been notified of the recall, the donating entity shall be responsible for notifying the qualifying center or clinic of the recall.

(c) Each qualifying center or clinic in possession of any unused medication that is expired, adulterated, or recalled shall make a manifest for and destroy that medication.

(d) Following the destruction of any unused medications, the manifest shall be signed by the consulting pharmacist and a witness to verify the destruction. Each drug destruction manifest shall be maintained for at least five years. (Authorized by and implementing L. 2008, ch. 9, §7; effective Jan. 2, 2009.)

Article 19.—RESERVED

Article 20.—CONTROLLED SUBSTANCES

68-20-1. Definitions. The following terms in this regulation shall have the meanings specified: (a) "Act" means the uniform controlled substances act of Kansas, K.S.A. 65-4101, et seq., and amendments thereto;

(b) "Basic class" means, as to controlled substances listed in schedules I and II:

(1) each of the opiates, including its isomers, esters, ethers, and salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation listed in K.S.A. 65-4105(b) and amendments thereto;

(2) each of the opium derivatives, including its salts and isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation listed in K.S.A. 65-4105(c) and amendments thereto;

(3) each of the hallucinogenic substances, including its salts and isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation listed in K.S.A. 65-4105(d) and amendments thereto;

(4) each of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;

(B) apomorphine;

(C) codeine;

(D) ethylmorphine;

(E) hydrocodone;

(F) hydromorphone;

(G) metopon;

(H) morphine;

(I) oxycodone;

(J) oxymorphone;

(K) thebaine;

(L) mixed alkaloid of opium listed in K.S.A. 65-4107(b)(1) and amendments thereto;

(M) cocaine; and

(N) ecgonine;

(5) each of the opiates, including its isomers, esters, ethers, and salts, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation listed in K.S.A. 65-4107(c) and amendments thereto;

(6) methamphetamine, including its salts, isomers, and salts of isomers, when contained in any injectable liquid;

(7) amphetamine, its salts, optical isomers and salts of its optical isomers;

(8) phenmetrazine and its salts; and

(9) methylphenidate.

(c) "Controlled premises" means:

(1) places where original or copies of records or documents required under the act are kept or required to be kept; and

(2) places where persons who are registered under the act or who are exempted from registration under the act may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances. Such places shall include factories, warehouses, establishments and conveyances.

(d) "Secretary" means the executive secretary of the state board of pharmacy of the state of Kansas.

(e) "Prescription" means an order for medication which is dispensed to or for an ultimate user, but does not include an order for medication which is dispensed for immediate administration to the ultimate user. An order for a single dose of a drug for immediate administration to a bed patient in a medical care facility shall not be construed to be a prescription.

(f) "Register" and "registration" mean only registration required and permitted under the controlled substances act. K.S.A. 65-4117.

(g) "Registrant" means any person who is registered pursuant to the act K.S.A. 65-4117.

(h) "Bureau" and "BNDD" mean the bureau of narcotics and dangerous drugs.

(i) "Preceptor" means a licensed pharmacist who has been approved, by the board, for the supervision of students who are securing the pharmaceutical experience required by law as a condition precedent to taking the examination for licensure as a pharmacist.

(j) Any term not defined in this regulation shall have the meaning as set forth in the act. To the extent definitions are not in conflict with any provision of the act, terms shall also have the meanings set forth in the pharmacy act of the state and Kansas and amendments thereto.

(k) This regulation shall be effective on May 1, 1989. (Authorized by K.S.A. 65-4102; implementing K.S.A. 65-4101; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended May 1, 1985; amended May 1, 1989.)

68-20-2 to 68-20-4. (Authorized by K.S.A. 65-4102; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; revoked May 1, 1983.)

68-20-5. (Authorized by K.S.A. 1977 Supp. 65-4115; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; revoked May 1, 1983.)

68-20-6. (Authorized by K.S.A. 1977 Supp. 65-4115; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended, E-77-42, Sept. 9, 1976; amended Feb. 15, 1977; amended May 1, 1978; revoked May 1, 1983.)

68-20-7. (Authorized by K.S.A. 65-4102; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; revoked May 1, 1983.)

68-20-8. (Authorized by K.S.A. 1976 Supp. 65-4102; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; revoked, E-77-42, Sept. 9, 1976; revoked Feb. 15, 1977.)

68-20-8a. (Authorized by K.S.A. 1977 Supp. 65-4115; effective May 1, 1978; revoked May 1, 1983.)

68-20-8b and 68-20-8c. (Authorized by K.S.A. 1976 Supp. 65-4115; effective, E-77-42, Sept. 9, 1976; effective Feb. 15, 1977; rejected, L. 1977, ch. 320, May 13, 1977.)

68-20-9. Fees for registration and reregistration. (a) Fee amounts.

(1) For each registration or reregistration of a manufacturer for each additional location in this state where controlled substances are manufactured, the registrant shall pay a fee of $50.00.

(2) For each registration or reregistration of each additional location from which controlled substances are distributed, the registrant shall pay a fee of $50.00.

(3) For each registration or reregistration of each location within this state where research or instructional activities are conducted with controlled substances listed in schedules I through V, the registrant shall pay a fee of $50.00.

(4) For each registration or reregistration to conduct chemical analysis with controlled substances listed in schedules I through V, as set out in K.S.A. 65-4105, K.S.A. 65-4107, K.S.A. 65-4109, K.S.A. 65-4111, K.S.A. 65-4113 and amendments thereto, within this state, the registrant shall pay a fee of $50.00.

(b) Time and method of payment; refund.

(1) Registration and reregistration fees shall be

paid at the time the application for registration or reregistration is submitted for filing.

(2) Payment shall be made in the form of a personal, certified, cashier's check or a money order payable to the state board of pharmacy.

(3) Payments made in the form of stamps, foreign currency or third party endorsement checks shall not be accepted.

(4) If the application is not accepted for filing or is denied, all payments made under paragraphs (1) through (4) of subsection (a) shall be refunded to the applicant.

(c) Exemptions from fees in paragraphs (1) through (4) of subsection (a).

(1) Any official or agency of the U.S. army, navy, marine corps, air force, coast guard, veteran's administration, or public health service authorized to procure or purchase controlled substances for official use shall be exempted by the board from the fees set forth in subsection (a), paragraphs (1) through (4).

(2) Any official, employee, or other civil service or agency of the United States, or any state, or any political subdivision or agency thereof, authorized to dispense or administer such substances, to conduct research, instructional activities, or chemical analysis with such substances, or any combination thereof, in the course of the official duties of employment, may be exempted by the board from the fees in subsection (a), paragraphs (1) through (4).

(d) In order to claim exemption from payment of a registration or reregistration fee, the registrant shall have completed the certification on the appropriate application forms. The registrant's superior shall certify the status and address of the registrant and shall certify to the authority of the registrant to acquire, possess, or handle controlled substances.

(e) Exemption from the payment of a registration or reregistration fee shall not relieve the registrant of any other requirements or duties prescribed by law. (Authorized by and implementing K.S.A. 65-4116; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended May 1, 1983; amended May 1, 1986; amended June 6, 1994.)

68-20-10. Requirements of registration. (a) Persons required to register. Every person who manufactures, distributes, or dispenses any controlled substances within this state, or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance in this state shall obtain annually a registration unless exempted by law or pursuant to subsections (d) through (g) of this regulation. Only persons actually engaged in these activities in this state shall be required to obtain a registration.

(b) Separate registration for independent activities.

(1) The following six groups of activities shall be deemed to be independent of each other:

(A) Manufacturing controlled substances;

(B) distributing controlled substances;

(C) dispensing, conducting research, other than research described in paragraph (b)(1)(D), with, and conducting instructional activities with, controlled substances listed in schedules II through V;

(D) conducting research with narcotic drugs listed in schedules II through V for the purpose of continuing the dependence on these drugs of a narcotic drug-dependent person in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program pursuant to a notice of claimed investigational exemption for a new drug approved by the food and drug administration;

(E) conducting research and instructional activities with controlled substances listed in schedule I; and

(F) conducting chemical analysis with controlled substances listed in any schedule.

(2) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this subsection (b). Any person, when registered to engage in the group of activities described in each paragraph in this subsection, shall be authorized to engage in the coincident activities described in that paragraph without obtaining a registration to engage in such coincident activities if, unless specifically exempted, the person complies with all requirements and duties prescribed by law for the following persons registered to engage in the coincident activities:

(A) A person registered to manufacture any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class that the person is not registered to manufacture.

(B) A person registered to manufacture any controlled substance listed in schedules II through V shall be authorized to conduct chemical analysis and preclinical research, including quality

control analysis, with narcotic and nonnarcotic controlled substances listed in those schedules in which the person is authorized to manufacture.

(C) A person registered to conduct research with a basic class of controlled substances listed in schedule I shall be authorized to manufacture this class if and to the extent that the manufacture is set forth in the research protocol filed with the application for registration and to distribute this class to other persons registered to conduct research with this class or to conduct chemical analysis.

(D) A person registered to conduct chemical analysis with controlled substances shall be authorized to perform the following:

(i) Manufacture and import these substances for analytical or instructional purposes;

(ii) distribute these substances to other persons registered to conduct chemical analysis or instructional activities, to persons registered or authorized to conduct research with these substances, and to persons exempted from registration pursuant to subsection (c);

(iii) export these substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries; and

(iv) conduct instructional activities with controlled substances.

(E) A person registered or authorized to conduct research, other than the research described in paragraph (b)(2)(C), with controlled substances listed in schedules II through V shall be authorized to perform the following:

(i) Conduct chemical analysis with controlled substances listed in those schedules in which the person is authorized to conduct research to manufacture is set forth in a statement filed with the application for registration;

(ii) distribute these substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with these substances and to persons exempted from registration pursuant to subsection (c); and

(iii) conduct instructional activities with controlled substances.

(F) A person registered to dispense under the pharmacy act, or to conduct research, other than research described in paragraph (b)(2)(D), with controlled substances listed in schedules II through V shall be authorized to dispense and to conduct research and to conduct instructional research with those substances.

(3) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in schedule I may conduct research with any substance listed in schedule I for which the person has filed and had approved a research protocol.

(c) Separate registrations for separate locations.

(1) A separate registration shall be required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, or dispensed by a person.

(2) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(A) A warehouse where controlled substances are stored by or on behalf of a registered person, unless these substances are distributed directly from the warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of the pharmacy act, K.S.A. 65-4116 and amendments thereto;

(B) an office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains these substances, other than substances for display purposes only, nor serves as a distribution point for filling sales orders; and

(C) an office used by a practitioner or mid-level practitioner who is registered at another location where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner or mid-level practitioner at this office, and where no supplies of controlled substances are maintained.

(d) Exemption of agents and employees; affiliated practitioners.

(1) Practitioners, mid-level practitioners, pharmacists, and other persons required to register under this act shall not be exempt from registration because of their status as an agent or employee of a person who is already registered to engage in any group of independent activities. The requirements of registration, however, shall be waived for any agent or employee of a person who is registered to engage in any group of independent activities, if the agent or employee is

acting in the usual course of his business or employment.

(2) A practitioner who is an intern, resident, or foreign physician or medical graduate may dispense and prescribe controlled substances under the registration of the hospital or other institution that is registered and by whom the person is employed if all of the following conditions are met:

(A) The practitioner is authorized or permitted to do so by the laws of the state of Kansas.

(B) The dispensing or prescribing is done in the usual course of the practitioner's professional practice.

(C) The hospital or other institution by whom the person is employed has determined that the practitioner is permitted to dispense or prescribe drugs by the state of Kansas.

(D) The practitioner is acting only within the scope of employment in the hospital or institution.

(E) The hospital or other institution authorizes the intern, resident, or foreign physician or medical graduate to dispense or prescribe under the hospital registration and designates a specific internal registration code number for each intern, resident, or foreign physician or medical graduate so authorized. The code number shall consist of numbers, letters, or a combination of both and shall be a suffix to the institution's drug enforcement administration registration number, preceded by a hyphen.

(F) A current list of internal codes and the corresponding practitioners is kept by the hospital or other institution, and an updated copy is on file with the state board of pharmacy of the state of Kansas for the purposes of verifying the authority of the prescribing practitioner.

(e) Exemption of certain military and other personnel.

(1) The requirement of registration shall be waived for any official of the U.S. army, navy, marine corps, air force, coast guard, or public health service who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of official duties. These officials shall follow the procedures set forth in K.A.R. 68-20-18, 68-20-19, 68-20-20, and 68-20-21, but shall state the branch of service or agency and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a public health service employee is the person's social security identification number.

(2) If any official exempted by this subsection also engages as a private individual in any activity or group of activities for which registration is required, the official shall obtain a registration for these private activities.

(f) Exemption of law enforcement officials.

(1) The requirement of registration shall be waived for the following persons in the circumstances described in this subsection:

(A) Any officer or employee of the bureau, any officer of the U.S. bureau of customs, any officer or employee of the United States food and drug administration, and any other federal officer who is lawfully engaged in the enforcement of any federal law relating to controlled substances, drugs, or customs, and is duly authorized to possess controlled substances in the course of official duties; and

(B) any officer or employee of the state of Kansas, or any political subdivision or agency thereof, who is engaged in the enforcement of Kansas law or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of official duties.

(2) Any official exempted by this subsection may, when acting in the course of official duties, possess any controlled substance and distribute any such substance to any other official who is also exempted by this subsection and acting in the course of official duties.

(3) Any official exempted by this subsection may procure any controlled substance in the course of an inspection, in accordance with the controlled substances act, K.S.A. 65-4131(c) and amendments thereto, or in the course of any criminal investigation involving the person from whom the substance was procured.

(4) In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use as standards in chemical analysis, these laboratories shall obtain annually a registration to conduct chemical analysis. These laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, shall be deemed to be officials exempted by this subsection and within the activities described in the controlled substances act, K.S.A. 65-4115 and amendments thereto. For purposes of this subsection, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this subsection.

(g) Exemption of civil defense officials.

(1) The requirement of registration shall be waived for any official of a civil defense or disaster relief organization who, in the course of official duties, is authorized to perform either of the following:

(A) Maintain, and distribute for maintenance, controlled substances held for emergency use; or

(B) procure controlled substances for the purposes of maintaining supplies for emergency use, if all procurement is from the U.S. general services administration and in accordance with the rules of the U.S. office of emergency preparedness.

(2) The requirement of registration shall be waived for any official of a civil defense or disaster relief organization during a state of emergency or disaster within the official's jurisdiction proclaimed by the president or by a concurrent resolution of the congress, which official, in the course of official duties during this emergency or disaster, is authorized to perform either of the following:

(A) Dispense controlled substances; or

(B) procure or distribute controlled substances, if all procurement is on a special "civil defense emergency order form," as described in this subsection.

(3) Civil defense emergency order forms shall be furnished by the U.S. office of emergency preparedness and shall contain the name of the civil defense or disaster relief organization. These forms may be used and shall be valid only during a state of emergency disaster proclaimed by the president or by a concurrent resolution of the congress for the area in which the organization using the forms has civil defense or disaster relief jurisdiction, who shall state the position and the nature and legal designation of the emergency or disaster. These forms may be filled by any person registered under the controlled substances act. The organization shall, upon the execution of a civil defense emergency order form, be deemed to be registered under the controlled substances act for purposes of record keeping pursuant to K.A.R. 68-20-16. (Authorized by K.S.A. 65-4116, as amended by L. 1999, Ch. 149, Sec. 9; implementing K.S.A. 65-4116, as amended by L. 1999, Ch. 149, Sec. 9, 65-4131; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended Dec. 27, 1999.)

68-20-10a. Electronic prescription transmission of controlled substances. (a) A prescription drug order transmitted electronically shall be issued for a legitimate medical purpose by a prescriber acting within the course of legitimate professional practice.

(b) All prescription drug orders communicated by way of electronic transmission shall fulfill all the requirements of K.A.R. 68-2-22.

(c) If communicated by electronic transmission, the prescription drug order shall be maintained in hard copy for the time required by existing federal and state laws and regulations.

(d) A prescription drug order, including that for any controlled substance listed in schedules III, IV, and V, and in certain situations, that for any controlled substance listed in schedule II, may be communicated by electronic transmission.

(e) The electronic transmission of a prescription drug order for any schedule II controlled substance shall conform to these requirements:

(1) A prescription drug order for any schedule II controlled substance may be communicated by the prescriber or that prescriber's designated agent by way of electronic transmission, if the original, written, signed prescription drug order is presented to the pharmacist for review before the actual dispensing of the controlled substance, except as noted in this subsection.

(2) A prescription drug order for any schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be communicated by the prescriber or that prescriber's designated agent to the pharmacy by way of electronic transmission. The hard copy of this electronic transmission shall serve as the original, written prescription drug order for purposes of this subsection, and it shall be maintained as such.

(3) A prescription drug order for any schedule II controlled substance for a resident of a long-term care facility (LTCF) may be communicated by the prescriber or that prescriber's designated agent by way of electronic transmission. The hard copy of this electronic transmission shall serve as the original, written prescription drug order for purposes of this subsection, and it shall be maintained as such.

(4) A prescription drug order for any schedule II controlled substance for a patient released by a registered institution to a home hospice setting that continues to provide daily skilled nursing care to the home hospice setting may be transmitted by the prescriber or that prescriber's designated

agent by way of electronic transmission to the dispensing pharmacy. The hard copy of this electronic transmission shall serve as the original, written prescription drug order for purposes of this subsection, and it shall be maintained as such.

(5) In the case of an emergency situation, a prescription drug order for any schedule II controlled substance may be communicated by the prescriber by way of electronic transmission, if these conditions are met:

(A) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period shall be pursuant to a written prescription drug order signed by the prescriber.

(B) After the pharmacist views the prescription drug order, this order shall be immediately reduced to a hard copy and shall contain all information required by federal and state laws and regulations.

(C) The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order communicated by way of electronic transmission, consistent with existing federal and state laws and regulations.

(D) (i) Within seven days after authorizing an emergency prescription drug order, the prescriber shall cause a written prescription drug order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to all other federal and state laws and regulations, the prescription drug order shall have written on its face "authorization for emergency dispensing" and the date of the transmitted prescription drug order.

(ii) The written prescription drug order shall be delivered to the pharmacist in person within seven days of authorization, or if delivered by mail, it shall be postmarked within the seven-day period.

(iii) Upon receipt, the dispensing pharmacist shall attach this written prescription drug order to the hard copy of the electronically transmitted prescription drug order. The pharmacist shall notify the nearest office of the U.S. drug enforcement administration (DEA) if the prescriber fails to deliver a written prescription drug order. (Authorized by and implementing K.S.A. 65-1630, K.S.A. 1998 Supp. 65-1642, K.S.A. 1998 Supp. 65-4102 and K.S.A. 65-4123, as amended by L. 1999, Ch. 115, Sec. 15; effective Feb. 5, 1999; amended Dec. 27, 1999.)

68-20-11. Applications for registration. (a) The expiration date of all registrations shall be the last day of June in each year.

(b) Each application for the following types of registration shall include the controlled substances code number for each basic class or substance to be covered by the registration:

(1) Registration to handle any basic class of controlled substances listed in schedule I, except registration to conduct chemical analysis with such classes;

(2) registration to manufacture a basic class of controlled substances listed in schedules II through V; and

(3) registration to conduct research with any narcotic controlled substance in schedules II through V.

(c) Each application, attachment, or other document filed as part of an application, shall be signed by:

(1) the applicant, if an individual;

(2) the authorized representative, if the registration is for a location;

(3) a partner of the applicant, if a partnership; or

(4) by an officer of the applicant, if a corporation, corporate division, association, trust or other entity.

(d) Any applicant may authorize one or more individuals to sign applications for the applicant or location by filing, with the executive secretary of the board, a power of attorney for each such individual. The power of attorney shall contain the signature of the individual who shall be authorized to sign applications pursuant to that power of attorney. The power of attorney shall be valid until revoked by the applicant.

(e) Any person required to obtain more than one registration may submit all applications in one package. Each application shall be completed and should not refer to any accompanying application for required information.

(f) Applications submitted for filing shall be dated upon receipt. Completed applications shall be accepted for filing. If completed with only minor defects, the board may accept the application for filing and send a request to the applicant for additional information. A defective application shall be returned to the applicant within 10 days following its receipt with a statement of the reason

for refusal to accept the application for filing. A defective application may be corrected and resubmitted for filing at any time.

(g) Additional information. The board may require any applicant or the applicant's authorized representative to submit such documents or written statements of fact relevant to the application as it deems necessary to determine whether the application should be granted. The failure of the applicant or authorized representative to provide the documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver of an opportunity to present the documents or facts for consideration by the board in granting or denying the application.

(h) Amendments to and withdrawal of applications.

(1) Any application may be amended or withdrawn without permission of the board at any time before the date on which the applicant or the applicant's authorized representative receives an order to show cause pursuant to K.S.A. 65-4119. Any application may be amended or withdrawn with permission of the board at any time good cause is shown by the applicant or the applicant's authorized representative, or when the amendment or withdrawal is in the public interest.

(2) After an application has been accepted for filing, a request by the applicant or the applicant's authorized representative for return of the application or failure of the applicant or authorized representative to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application. (Authorized by and implementing K.S.A. 65-4116 as amended by L. 1987, Ch. 244, Sec. 3; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended May 1, 1985; amended May 1, 1988.)

68-20-12. (Authorized by K.S.A. 65-4116, 65-4117, 65-4118, 65-4119; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; revoked May 1, 1987.)

68-20-13. Hearings generally. In any case where the board shall hold a hearing on any registration or application therefor, the procedures for such hearing shall be conducted in accordance with the procedural provisions of the act and paragraph 68-20-13 of these regulations. Any hearing under this part shall be independent of and not in lieu of, criminal proceedings or other proceedings under the act or any other law of this state.

(A) *Purpose of hearing*—The board shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

(B) *Waiver or modification of rules*—The board or its presiding officer (with respect to matters pending before him), may modify or waive any rule or regulation in paragraph 68-20-13 of these regulations by notice in advance of the hearing, if the board determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the records of the hearing.

(C) *Hearing; waiver.* (1) Any person entitled to a hearing may file with the board a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(2) If any person entitled to a hearing or to participate in a hearing waives his opportunity to participate in the hearing, the board may proceed without the presence of such person.

(D) *Burden of proof.* (1) At any hearing for the denial of a registration, the board shall have the burden of proving that the requirements of such registration pursuant to the act (K.S.A. 65-4117, K.S.A. 65-4118) are not satisfied.

(2) At any hearing for the revocation or suspension of a registration, the board shall have the burden of proving that the requirements for such revocation or suspension in accordance with the provisions of the act (K.S.A. 65-4119).

(E) *Time and place of hearing*—The hearing will commence at the place and time designated in the order to show cause (unless expedited pursuant to paragraph 68-20-12D of these regulations) but thereafter, it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other

than announcement thereof by the presiding officer at the hearing.

(F) *Final order*—As soon as practicable after the presiding officer has certified the record to the board, the board shall issue its order on the granting, denial, revocation or suspension of the registration. In the event that any application for registration is denied, or any registration is revoked or suspended, the order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The board shall serve one copy of its order upon each party in the hearing by registered, return receipt requested mail. (Authorized by K.S.A. 65-4117, 65-4118, 65-4119; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973.)

68-20-14. Modification, transfer and termination of registration. (A) *Modification in registration*—Any registrant may apply to modify his registration to authorize the handling of additional controlled substances by submitting a letter of request to the state board of pharmacy. The letter shall contain the registrant's name, address, registration number and the substance and/or schedules to be added to his registration and shall be signed by the same person who signed the most recent application for registration or reregistration. If the registrant is seeking to handle additional controlled substances listed in schedule I for the purpose of research or instructional activities, he shall attach one copy of the federally approved research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent and duration of such instructional activities, as appropriate. One-half of the original fees shall be required to be paid for said modification. The request for modification shall be handled in the same manner as an application for registration.

(B) *Termination of registration*—The registration of any person or location shall terminate if and when such person or authorized representative of a location dies, ceases legal existence, discontinues business or professional practice or changes the location as shown on the certificate of registration. Any registrant who ceases legal existence, discontinues business or professional practice, or changes location as shown on the certificate of registration, shall notify the board promptly of such fact and forthwith deliver the certificate of registration directly to the secretary or executive secretary of the board. In the event of a change in name or mailing address the person or authorized representative of the location shall notify the board promptly in advance of the effective date of this change by filing the change of name or mailing address with the board. This change shall be noted on the original application on file with the board.

(C) *Transfer of registration*—No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the board may specifically designate and then only pursuant to its written consent. (Authorized by K.S.A. 65-4115; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973.)

68-20-15. (Authorized by K.S.A. 1976 Supp. 65-4115; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended, E-77-42, Sept. 9, 1976; amended Feb. 15, 1977; revoked May 1, 1983.)

68-20-15a. Security requirements. (a) General security requirements. Each applicant and registrant shall provide effective controls and procedures to guard against theft and diversion of controlled substances in conformance with the security requirements of federal law, including the requirements of 21 CFR 1301.71 as in effect on April 1, 1999, which are hereby adopted by reference.

(b) Physical security controls for nonpractitioners shall comply with the requirements of 21 CFR 1301.72 and 1301.73 as in effect on April 1, 1999, which are hereby adopted by reference.

(c) Other security controls for nonpractitioners.

(1) Good faith inquiry. Before distributing a controlled substance to any person whom the registrant does not know to be registered to possess a controlled substance, each registrant shall make a good faith inquiry with the board to determine that the person is registered to possess a controlled substance.

(2) Suspicious orders. Each registrant shall design an operative system to disclose to the registrant any suspicious orders of controlled substances. Each registrant shall inform the board of suspicious orders when discovered. Suspicious orders shall include orders of unusual size, orders deviating from a normal pattern, and orders of unusual frequency.

(3) A controlled substance listed in schedules II through V shall not be distributed on a gratui-

tous basis by a manufacturer or distributor to a practitioner, mid-level practitioner, pharmacist, or any other person.

(d) Physical security controls for prescribers. Each prescriber shall provide effective controls and procedures to guard against theft and diversion of controlled substances in conformance with the security requirements of federal law, including the requirements of 21 CFR 1301.75 and 1301.76 as in effect on April 1, 1999, which are hereby adopted by reference.

(e) Other security controls for prescribers.

(1) In order to minimize the opportunities for diversion of controlled substances, each prescriber shall provide effective physical security, shall initiate additional procedures to reduce access by unauthorized personnel, and shall provide an alarm system if necessary.

(2) Minimum security standards for prescribers as set forth in this article shall be considered as guidelines to be used in evaluating security. Additional security controls and operating procedures may be required by the board to prevent diversion of controlled substances. (Authorized by K.S.A. 1998 Supp. 65-4102; implementing K.S.A. 65-4117; effective May 1, 1983; amended May 1, 1988; amended Sept. 9, 1991; amended March 20, 1995; amended Aug. 1, 1997; amended Feb. 5, 1999; amended Dec. 27, 1999.)

68-20-16. Records and inventories of registrants. (a) Each registrant shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of 21 CFR 1304.04 as in effect on April 1, 1999, which is hereby adopted by reference, and shall be kept on file for a period of not less than five years.

(b) Schedule V preparations. All registrants handling Schedule V preparations shall be subjected to the same inventory and record-keeping requirements set forth in subsection (a) above. In addition, an inventory of Schedule V items shall be taken in conjunction with the required inventory requirements relating to Schedules II, III, and IV. (Authorized by and implementing K.S.A. 65-4121; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended May 1, 1989; amended July 31, 1998; amended Dec. 27, 1999.)

68-20-17. Order forms. Each transfer of any schedule I or II controlled substance shall require the use of a drug enforcement agency (DEA) 222 form issued by the United States attorney general in accordance with 21 CFR part 1305 or an electronic order placed in accordance with 21 CFR part 1311. (Authorized by K.S.A. 65-4102; implementing K.S.A. 65-4102 and K.S.A. 65-4122; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended May 1, 1987; amended Feb. 5, 1999; amended Dec. 27, 1999; amended April 27, 2007.)

68-20-18. Information concerning prescriptions. (a) Persons entitled to issue prescriptions. A prescription for a controlled substance may be issued only by a practitioner or mid-level practitioner who meets the following conditions:

(1) Is legally authorized to prescribe controlled substances in Kansas or any other competent jurisdiction; and

(2) is either registered or exempted from registration under K.S.A. 65-4116(d) and amendments thereto.

(b) Purpose of issue of prescription.

(1) To be effective, a prescription for a controlled substance shall be issued for a legitimate medical purpose by a practitioner or mid-level practitioner acting in the usual course of professional practice. The responsibility for the proper prescribing and dispensing of controlled substances shall rest with the prescriber, but a corresponding responsibility shall rest with the pharmacist who fills the prescription. The person filling an unlawful prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of the controlled substance act, K.S.A. 65-4101, et. seq. and amendments thereto.

(2) A prescription shall not be issued in order for a practitioner or mid-level practitioner to obtain controlled substances for supplying that individual or any other prescriber for the purpose of general dispensing to patients.

(3) A prescription shall not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug-dependent person for the purpose of continuing dependence upon these drugs, except in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

(c) Manner of issuance of prescriptions.

(1) Controlled substance prescriptions in schedules II through V shall not be issued on a prescription blank that is preprinted with the name of a propriety preparation or with the strength, quantity, or directions.

(2) All written prescriptions for controlled substances shall meet the following requirements:

(A) Be dated and manually signed on the day issued;

(B) bear the following information:

(i) The full name, address, and registration number of the practitioner or mid-level practitioner;

(ii) the name and address of the patient; and

(iii) the drug name, strength, dosage form, quantity prescribed, and directions for use; and

(C) be written with ink, indelible pencil, or typewriter.

(3) A practitioner or mid-level practitioner shall manually sign a prescription in the same manner as that individual would sign a check or legal document.

(4) The prescriptions may be prepared by a secretary or agent for the signature of a practitioner or mid-level practitioner, but the prescriber shall be responsible if the prescription does not conform in all essential respects to the state and federal law and regulations. A corresponding liability shall rest upon the pharmacist who fills a prescription that is not prepared in the form prescribed by this regulation.

(5) An intern, resident, foreign physician, or foreign medical graduate exempted from registration under K.S.A. 65-4116(d), and amendments thereto, shall include on all prescriptions issued the registration number of the hospital or other institution and the special internal code number assigned to the intern, resident, foreign physician, or foreign medical graduate by the hospital or other institution as provided in K.A.R. 68-20-10. This requirement shall be in lieu of the registration number of the practitioner required by this subsection. Each prescription shall have the name of the intern, resident, foreign physician or foreign medical graduate stamped or printed on it, as well as the signature of the physician.

(6) An official exempted from registration under K.A.R. 68-20-10 shall include on all prescriptions issued the official's branch of service or agency and the service identification number. This requirement shall be in lieu of the registration number of the practitioner otherwise required by this subsection. The service identification number for a public health service employee shall be that individual's social security identification number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer.

(d) Manner of issuance of prescriptions by facsimile.

(1) Controlled substance prescriptions in schedules III through V may be transmitted by telephone by a prescriber or designated agent to a pharmacy for a patient of the prescriber. The transmitted telephone prescription may be by oral, facsimile, or electronic transmission. Prescription orders shall be reduced to hard copy by the pharmacist and, if telephoned by other than the prescriber, shall bear the name of the person so transmitting or telephoning the prescription.

(2) Controlled substance prescriptions in schedule II may be transmitted by facsimile or electronic transmission from the prescriber to a pharmacy. However, when the prescription is actually dispensed, the original written prescription that is manually signed by the prescriber shall be presented, verified against the facsimile or electronic transmission, and retained for filing. Exceptions to this subsection shall be in compliance with K.A.R. 68-20-10a.

(e) Persons entitled to fill prescriptions.

(1) A prescription for controlled substances shall be filled only by the following:

(A) A pharmacist acting in the usual course of professional practice in a registered pharmacy, hospital drug room, or other registered place of employment; or

(B) a pharmacist intern acting under the immediate personal direction and supervision of a licensed pharmacist.

(2) For the purposes of this regulation, an intern shall mean a prospective candidate for examination as a licensed pharmacist who is qualified to receive, and is obtaining, pharmaceutical experience as defined in K.A.R. 68-5-1.

(3) A medical care facility or other institution registered with the board shall administer or dispense directly a controlled substance listed in schedules III and IV and legend V only pursuant to a written prescription signed by the prescriber or to an order of medication made by a prescriber that is dispensed for immediate administration to the ultimate user. (Authorized by K.S.A. 1998 Supp. 65-4102; implementing K.S.A. 65-4123, as amended by L. 1999, Ch. 115, Sec. 15; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended May 1, 1988; amended Sept. 9, 1991; amended March 29, 1993; amended March 20, 1995; amended Dec. 27, 1999.)

68-20-19. Controlled substances listed in schedule II. (a) Requirements of prescription.

(1) A pharmacist shall dispense a controlled substance listed in schedule II, which is a prescription drug as determined under these regulations, only pursuant to a written prescription signed by the prescribing practitioner, except as provided in paragraph (4) of this subsection.

(2) Any written prescriptions signed by the prescribing practitioner falling under the above provisions of paragraph (1) shall not be filled if submitted more than six months after the original date appearing on the written prescription.

(3) A prescriber may administer a controlled substance listed in schedule II in the course of professional practice without a prescription, subject to K.A.R. 68-20-18.

(4) (A) In the case of an emergency situation, as defined by paragraph (5) of this subsection, a pharmacist may dispense a controlled substance listed in schedule II upon receiving authorization of a prescriber, if all of the following conditions are met:

(i) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period shall be pursuant to a written prescription signed by the prescriber.

(ii) The prescription shall be immediately reduced to a hard copy by the pharmacist and shall contain all information required under K.A.R. 68-20-18(c) except for the signature of the prescriber.

(iii) If the prescriber is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the authorization came from the prescriber, which may include a call back to the prescriber, using the prescriber's phone number as listed in the telephone directory or other good faith efforts to insure the prescriber's identity, or both.

(iv) Within seven days after authorizing an emergency prescription drug order, the prescriber shall cause a written prescription drug order for the emergency quantity prescribed to be delivered to the dispensing pharmacist.

(B) In addition to conforming to the requirements of K.A.R. 68-20-18(c), the prescription drug order shall have written on its face "Authorization for Emergency Dispensing" and the date of the prescription drug order.

(C) The written prescription drug order shall be delivered to the pharmacist in person within seven days of authorization or, if delivered by mail, it shall be postmarked within the seven-day period.

(D) Upon receipt, the dispensing pharmacist shall attach this written prescription drug order to the pharmacist's record of the emergency prescription drug order.

(E) The pharmacist shall notify the nearest office of the U.S. drug enforcement administration (DEA) if the prescribing practitioner fails to deliver a written prescription drug order to the pharmacist; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescriber.

(5) For the purposes of authorizing a prescription of any controlled substance listed in schedule II of the federal or state uniform controlled substances act, the term "emergency situation" means those situations in which the prescriber determines the following:

(A) That immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user;

(B) that no appropriate alternative treatment is available, including administration of a drug that is not a controlled substance under schedule II of the act; and

(C) that it is not reasonably possible for the prescriber to provide a written prescription to be presented, before dispensing, to the pharmacist dispensing the substance.

(b) A medical care facility or other institution registered with the board shall administer or dispense a controlled substance listed in schedule II only pursuant to a written prescription signed by the prescriber or to an order for medication made by a prescriber that is dispensed for immediate administration to the ultimate user.

(c) Partial filling of prescriptions. The partial filling of a prescription for any controlled substance listed in schedule II shall be permissible, only as provided in this subsection.

(1) Whenever the pharmacist is unable to supply the full quantity called for in a written or emergency prescription and the pharmacist makes a notation of the quantity supplied on the face of the written prescription or written record of the emergency prescription, the pharmacist shall perform the following:

(A) Fill the remaining portion of the prescription within 72 hours of the first partial filling or, if the remaining portion cannot be filled within

the 72-hour period, the pharmacist shall notify the prescriber of the situation; and

(B) supply no further quantity beyond 72 hours without a new prescription.

(2) Whenever written, prescriptions for schedule II controlled substances for patients in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities, including individual dosage units, as provided in this subsection. The pharmacist shall record on the prescription whether the patient is "terminally ill" or an "LTCF patient."

(A) For each partial filling, the dispensing pharmacist shall record on the back of the prescription, or on another appropriate, uniformly maintained, and readily retrievable record, the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

(B) The total quantity of schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed.

(C) These schedule II prescriptions shall be valid for a period not to exceed 60 days from the issue date unless terminated sooner by the discontinuance of medication.

(d) Labeling of substances. The pharmacist filling a written or emergency prescription for a controlled substance listed in schedule II shall affix a label to the package showing the following information:

(1) The date the prescription was filled;

(2) the name, address, and telephone number of the pharmacy dispensing the prescription;

(3) the serial number of the prescription;

(4) the full name of the patient;

(5) the name of the practitioner and either the physician's assistant (PA) or the advanced registered nurse practitioner (ARNP);

(6) the directions for use and cautionary statements, if any, contained in the prescription or required by law;

(7) the brand name or corresponding generic name of the prescription medication;

(8) the manufacturer or distributor of the prescription medication, or an easily identified abbreviation of the manufacturer's or distributor's name;

(9) the expiration date of the prescription medication dispensed, if applicable.

(e) Filing of prescriptions.

(1) All written prescriptions and written records of emergency prescriptions shall be kept in accordance with K.A.R. 68-20-16.

(2) All written or emergency prescriptions for a controlled substance listed in schedule II shall be cancelled on the face of the prescription with the name of the pharmacist filling that prescription.

(3) All written or emergency prescriptions for controlled substances listed in schedule II and filled by a pharmacy intern shall be cancelled on the face of the prescription with the names of the pharmacy intern and preceptor authorizing the filling of that prescription. (Authorized by and implementing K.S.A. 1998 Supp. 65-4102 and K.S.A. 65-4123, as amended by L. 1999, Ch. 115, Sec. 15; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended Sept. 9, 1991; amended March 29, 1993; amended March 20, 1995; amended Feb. 5, 1999; amended Dec. 27, 1999.)

68-20-20. Controlled substances listed in schedules III and IV. (a) Requirements of prescription.

(1) A pharmacist may dispense any controlled substance listed in schedule III, IV, or V that is a prescription drug as determined under the federal food, drug, and cosmetic act, pursuant only to a written prescription signed by a prescriber, or an oral prescription made by a prescriber, and promptly reduced to writing by the pharmacist containing all information required under K.A.R. 68-20-18(c), except for the signature of the prescriber.

(2) A prescriber may administer any controlled substance listed in schedule III, IV, or V in the course of the practitioner's professional practice without a prescription, subject to K.A.R. 68-20-18.

(3) A medical care facility registered with the board may administer or dispense directly, but shall not prescribe, any controlled substance listed in schedule III, IV, or V only pursuant to a written prescription signed by the prescriber, or to an order for medication made by a prescriber for immediate administration to the ultimate user.

(b) Filling of prescriptions.

(1) Each refilling of a prescription shall be entered on the back of a prescription, with the following additional information:

(A) The date of refilling or dispensing;

(B) the amount dispensed; and

(C) the name or initials of the dispensing pharmacist or pharmacist intern.

(2) Additional quantities of controlled substances listed in schedules III or IV may be authorized by a prescriber through an oral refill authorization transmitted to the pharmacist if all of the following conditions are met:

(A) The total quantity authorized, including the amount of the original prescription, does not exceed five refills or extend beyond six months from the date of issue of the original prescription.

(B) The pharmacist obtaining the oral authorization records on the reverse of the original prescription the following:

(i) The date;

(ii) the quantity of refill;

(iii) the number of additional refills authorized; and

(iv) the initials of the pharmacist who received the authorization from the prescriber.

(C) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(D) The prescriber executes a new prescription as provided in K.A.R. 68-20-18 for any additional quantities beyond the five-refill, six-month limitation.

(3) As an alternative to the procedures provided by paragraph (b)(2), an automated data-processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in schedule III and IV, if all of the following requirements are met:

(A) Any such proposed computerized system shall provide on-line retrieval, via CRT display or hard-copy printout, of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include the following:

(i) The original prescription number;

(ii) the date of issuance of the original prescription order by the prescriber;

(iii) the full name and address of the patient;

(iv) the name, address, and DEA registration number of the prescriber;

(v) the name, strength, dosage form, quantity of the controlled substance prescribed, and the quantity dispensed, if different from the quantity prescribed; and

(vi) the total number of refills authorized by the prescriber.

(B) Any such proposed computerized system shall also provide on-line retrieval, via CRT display or hard-copy printout, of the current refill history for schedule III or IV controlled substance prescription orders that have been authorized for refill during the past six months. This refill history shall include the following information:

(i) The name of the controlled substance;

(ii) the date of refill;

(iii) the quantity dispensed;

(iv) the identification code, or name or initials of the dispensing pharmacist for each refill; and

(v) the total number of refills dispensed to date for that prescription order.

(C) Documentation that the refill information entered into the computer each time a pharmacist refills an original prescription order for a schedule III or IV controlled substance is correct shall be provided by the individual pharmacist who makes use of such a system. If this system provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled the prescription order. The individual pharmacist shall verify that the date indicated is correct and then sign this document in the same manner as the pharmacist would sign a check or legal document. This document shall be maintained in a separate file at the pharmacy for five years from the dispensing date. This printout of the day's controlled substance prescription order refill data shall be provided to each pharmacy using the computerized system within 72 hours of the date on which the refill was dispensed. This document shall be verified and signed by each pharmacist who is involved with the dispensing. In lieu of such a printout, the pharmacy shall maintain a bound logbook, or separate file, in which each individual pharmacist involved in the dispensing shall sign a statement, in the manner previously described, each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by the pharmacist and is correct as shown. This book or file shall be maintained at the pharmacy employing the system for five years after the date of dispensing the appropriately authorized refill.

(D) Any such computerized system shall have the capability of producing a printout of any refill data that the user pharmacy is responsible for maintaining. This shall include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance, by brand, generic name, or both. This printout shall include the following:

(i) The name of the prescriber;

(ii) the name and address of the patient;

(iii) the quantity dispensed on each refill;

(iv) the date of dispensing for each refill;

(v) the name or identification code of the dispensing pharmacist; and

(vi) the number of the original prescription order.

(E) In any central computerized system employed by a user pharmacy, the central recordkeeping location shall be capable of sending the printout to the pharmacy within 48 hours, and if an authorized agent of the board requests a copy of this printout from the user pharmacy, it shall, if requested to do so by the agent, verify the printout transmittal capability of its system by documentation.

(F) If a pharmacy that employs such a computerized system experiences system downtime, the pharmacy shall have an auxiliary procedure that will be used for documentation of refills of schedule III and IV controlled substance prescription orders. This auxiliary procedure shall insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(4) When filing refill information for original prescription orders for schedule III or IV controlled substances, a pharmacy may use one of the two systems described in paragraphs (2) or (3) of this subsection.

(5) In the case of medical care facilities registered with the board, all requirements specified in paragraphs (b) (1), (2), and (3) above shall be maintained in the medication records or other readily retrievable records regularly maintained by the medical care facility.

(c) Partial filling of prescriptions. A prescription for a controlled substance listed in schedule III, IV, or V may be partially filled if all of the following conditions are met:

(1) Each partial filling is recorded in the same manner as a refilling.

(2) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(3) Except for a controlled substance listed in schedule V, no dispensing occurs after six months after the date on which the prescription was issued.

(d) Labeling of substances. The pharmacist filling a prescription for a controlled substance listed in schedule III or IV shall affix to the package a label showing the following:

(1) The pharmacy name and address;

(2) the serial number of the prescription;

(3) the date of initial filling;

(4) the name of the patient;

(5) the name of the prescriber issuing the prescription;

(6) the directions for use; and

(7) cautionary statements, if any, contained in the prescription as required by law, except as provided in 21 CFR 1306.24 as in effect on April 1, 1999, which is hereby adopted by reference.

(e) Filing prescriptions. All prescriptions for controlled substances listed in schedules III, IV, and V shall be kept in accordance with K.A.R. 68-20-16. (Authorized by and implementing K.S.A. 1998 Supp. 65-4102, K.S.A. 65-4121, K.S.A. 65-4123; effective, E-73-24, Aug. 25, 1972; effective Jan. 1, 1973; amended May 1, 1983; amended April 30, 1990; amended Aug. 4, 2000.)

68-20-21. Controlled substances listed in schedule V. Requirements of prescriptions.

(a) A pharmacist may dispense a controlled substance listed in schedule V pursuant to a prescription as required for controlled substances listed in schedules III and IV in K.A.R. 68-20-20 in this article. A prescription for a controlled substance listed in schedule V may be refilled only as expressly authorized by the prescriber on the prescription; if no such authorization is given, the prescription shall not be refilled. A pharmacist dispensing this substance pursuant to a prescription shall label the substance in accordance with subsection (d) of K.A.R. 68-20-20 in this article and file the prescription in accordance with K.A.R. 68-20-16 in this article.

(b) A prescriber may administer a controlled substance listed in schedule V in the course of professional practice without a prescription, subject to subsection (e) of K.A.R. 68-20-18 in this article.

(c) A hospital or other institution registered with the board may administer or dispense any controlled substance listed in schedule V only pursuant to a written prescription signed by the prescriber or to an order for medication made by a prescriber that is dispensed for immediate administration to the ultimate user. (Authorized by K.S.A. 1998 Supp. 65-4113; effective, E-72-24,

Aug. 25, 1972; effective Jan. 1, 1973; amended Dec. 27, 1999.)

68-20-22. Dispensing without prescription. A controlled substance listed in schedule V and a controlled substance listed in schedule II, III or IV which is not a prescription drug as determined under the federal food, drug, and cosmetic act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such dispensing is made only by a pharmacist as that term is defined by the pharmacy act of the state of Kansas and not by a non-pharmacist employee, even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his or her professional and legal responsibilities set forth in this act, the actual cash, credit transaction, or delivery, may be completed by a non-pharmacist.

(b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces), of any other such controlled substance nor more than forty-eight (48) dosage units of any such controlled substance containing opium, nor more than twenty-four (24) dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given forty-eight (48) hour period.

(c) The purchaser is at least eighteen (18) years of age.

(d) The pharmacist requires every purchaser of a controlled substance under this section not known to him or her to furnish suitable identification (including proof of age where appropriate).

(e) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the record keeping requirements of the uniform controlled substances act of the state of Kansas);

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other federal, state or local law. (Authorized by K.S.A. 1977 Supp. 65-4116; effective May 1, 1978.)